



FEDERAL REGISTER

Vol. 90

Friday,

No. 227

November 28, 2025

Pages 54523–55040

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: 90 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. 90, No. 227

Friday, November 28, 2025

Agency for Healthcare Research and Quality

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54690–54692

Agriculture Department

See Federal Crop Insurance Corporation

Bureau of Consumer Financial Protection

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54643–54644

Centers for Medicare & Medicaid Services

RULES

Medicare and Medicaid Programs:

Calendar Year 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Correction, 54589–54590

PROPOSED RULES

Medicare Program:

Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, 54894–55030

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54693–54695

Medicare Program:

Inflation Reduction Act Medicare Drug Price Negotiation Program Final Guidance, 54692

Privacy Act; Matching Program:

Correction, 54692–54693

Civil Rights Cold Case Records Review Board

NOTICES

Formal Determination on Records Release, 54634–54635

Coast Guard

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54721–54731

Commerce Department

See Foreign-Trade Zones Board

See Patent and Trademark Office

Committee for Purchase From People Who Are Blind or Severely Disabled

NOTICES

Procurement List; Additions and Deletions, 54638–54640

Commodity Futures Trading Commission

NOTICES

Privacy Act; Systems of Records, 54640–54643

Comptroller of the Currency

NOTICES

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

Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of 250 Billion Dollars or More under the Dodd-Frank Wall Street Reform and Consumer Protection Act, 54886–54887

Request for Information:

Community Banks' Engagement with Core Service Providers and Other Essential Third-Party Service Providers, 54882–54886

Consumer Product Safety Commission

NOTICES

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

Safety Standard for Clothing Storage Units, 54644–54645

Copyright Royalty Board

RULES

Cost of Living Adjustment to Public Broadcasters

Compulsory License Royalty Rate, 54585–54586

Drug Enforcement Administration

NOTICES

Aggregate Production Quotas:

Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2026, 54745–54760

Education Department

NOTICES

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

Form for Maintenance of Effort Waiver Requests, 54646

Energy Department

See Federal Energy Regulatory Commission

Environmental Protection Agency

RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

Montana; Regional Haze Plan for the Second Implementation Period, 54586–54588

Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category; Withdrawal, 54588

PROPOSED RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

Connecticut; New Source Review Permit Program State Plan Revision, 54609–54611

Missouri; Reporting Emission Data, Emission Fees, and Process Information, 54605–54607

Virginia; Repeal of Existing Stationary Source Regulations, 54607–54609

Hazardous and Solid Waste Management System:
Disposal of Coal Combustion Residuals from Electric
Utilities; Extension of an Alternative Closure
Requirement Deadline, 54611–54619

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
State Program Adequacy Determination: Municipal Solid
Waste Landfills and Non-Municipal, Non-Hazardous
Waste Disposal Units that Receive Conditionally
Exempt Small Quantity Generator Hazardous Waste,
54678–54680

Environmental Impact Statements; Availability, etc., 54678
Federal Agency Hazardous Waste Compliance Docket,
54680–54683

Funding Availability:

Credit Assistance under the State Infrastructure
Financing Authority Water Infrastructure Finance
and Innovation Act Program, 54675–54678
Credit Assistance under the Water Infrastructure Finance
and Innovation Act Program, 54671–54675

Export-Import Bank**NOTICES**

Applications for Long-Term Loans or Financial Guarantees
in Excess of \$100 million, 54683

Federal Aviation Administration**RULES**

Airworthiness Directives:
Airbus SAS Airplanes, 54549–54552, 54559–54563,
54568–54571
Dassault Aviation Airplanes, 54545–54548
The Boeing Company Airplanes, 54552–54559, 54563–
54568

PROPOSED RULES

Airworthiness Directives:
Airbus Helicopters, 54591–54593, 54596–54599, 54601–
54603
Schempp-Hirth Flugzeugbau GmbH Gliders, 54593–54596
Textron Aviation, Inc. (Type Certificate Previously Held
by Cessna Aircraft Company) Airplanes, 54599–
54601

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Service Availability Prediction Tool, 54839–54840
Petition for Exemption; Summary:
Rotor Technologies, Inc., 54839

Federal Communications Commission**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 54683–54686
Empowering Local Broadcast TV Stations to Meet Their
Public Interest Obligations:
Exploring Market Dynamics Between National
Programmers and Their Affiliates, 54686–54688
Intent to Dismiss Certain Older Petitions and Applications
Related to the Telephone Consumer Protection Act,
54683

Federal Crop Insurance Corporation**RULES**

Expanding Access to Risk Protection, 54523–54544

Federal Deposit Insurance Corporation**RULES**

Official Signs and Advertising Requirements, False
Advertising, Misrepresentation of Insured Status, and
Misuse of the Federal Deposit Insurance Corporation's
Name or Logo, 54544–54545

NOTICES

Designated Reserve Ratio for 2026, 54688–54689
Meetings; Sunshine Act, 54688–54689

Federal Energy Regulatory Commission**NOTICES****Application:**

Columbia Gas Transmission, LLC, 54650–54652, 54668–
54670
Pacific Gas and Electric Co., 54662
Combined Filings, 54648–54649, 54653–54654, 54663,
54667–54668

Environmental Assessments; Availability, etc.:

Northern States Power Co., 54670–54671

Environmental Issues:

Enable Mississippi River Transmission, LLC; Big Hollow
Project, 54656–54658

Hearings, Meetings, Proceedings, etc.:

California Department of Water Resources, 54650
Federal and State Current Issues Collaborative, 54658
Institution of Section 206 Proceeding and Refund Effective
Date:

Puget Sound Energy, Inc., 54664–54665

Request under Blanket Authorization:

National Fuel Gas Supply Corp., 54646–54648
Rockies Express Pipeline, LLC, 54663–54664
Saltville Gas Storage Co. LLC, 54654–54656

Scoping Period:

Columbia Gulf Transmission, LLC, 54665–54667
Corpus Christi Liquefaction Stage IV, LLC; Corpus Christi
Liquefaction, LLC; Cheniere Corpus Christi Pipeline,
L.P., 54658–54661

Termination of Exemption:

James D. Sysko, 54652–54653

Federal Motor Carrier Safety Administration**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Quantifying the Benefits of Creating New Truck Parking
Spaces, 54850–54852
Exemption Application:
Qualification of Drivers; Hearing, 54841–54850, 54852–
54859

Federal Reserve System**NOTICES****Change in Bank Control:**

Acquisitions of Shares of a Bank or Bank Holding
Company, 54689–54690
Formations of, Acquisitions by, and Mergers of Bank
Holding Companies, 54689–54690

Fiscal Service**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Application Form for U.S. Department of the Treasury
Accountable Official Stored Value Card Program,
54889–54890
Application Forms for U.S. Department of the Treasury
Stored Value Card Program, 54888

Description of United States Savings Bonds Series HH/H and Description of United States Bonds/Notes, 54890
Electronic Funds Transfer Market Research Study, 54889
Request to Reissue United States Savings Bonds, 54888

Food and Drug Administration

PROPOSED RULES

Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products; Withdrawal, 54603–54604

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Center for Devices and Radiological Health Appeals Processes, 54695–54696

Foreign-Trade Zones Board

NOTICES

Approval of Subzone Status:
Coroplast Tape Corp., Rock Hill, SC, 54635–54636
Elite Logistix, LLC, Rock Hill, SC, 54635

Health and Human Services Department

See Agency for Healthcare Research and Quality
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health

NOTICES

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2026, through September 30, 2027, 54696–54699

Homeland Security Department

See Coast Guard
See U.S. Citizenship and Immigration Services

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
SAFECOM Nationwide Surveys Generic Clearance, 54732–54733
Visitor Request Form, 54731–54732

Interior Department

See Land Management Bureau
See National Indian Gaming Commission
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service

PROPOSED RULES

Furnishing Identifying Number of Tax Return Preparer; Withdrawal, 54604–54605

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
U.S. Withholding Tax Return for Disposition by Foreign Persons of U.S. Real Property Interests and Statement of Withholding on Dispositions by Foreign Persons of U.S. Real Property Interests, 54890–54891

International Trade Commission

NOTICES

Investigations; Determinations, Modifications, and Rulings, etc.:
Certain Liquid Crystal Display Devices, Components Thereof, and Products Containing the Same, 54742–54743

Certain Microcurrent Facial Toning Devices and Systems Thereof, 54744

Lightweight Thermal Paper from China; Revised Schedule for the Subject Proceeding, 54745
Quartz Surface Products from India and Turkey, 54744–54745

Performance Review Board Members, 54742

Justice Department

See Drug Enforcement Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application to Transport Interstate or to Temporarily Export Certain NFA Firearms, 54761–54762
Explosives Licensee/Permittee Out-of-Business Records, 54760–54761
Identifying/Marking Explosive Materials, 54762–54763
Juvenile Facility Census Program, 54764–54765
National Response Team Customer Satisfaction Survey, 54763–54764

Land Management Bureau

NOTICES

Oil and Gas Lease:
NMNM 141402, New Mexico, Proposed Reinstatement, 54739

Library of Congress

See Copyright Royalty Board

Maritime Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Determination of Fair and Reasonable Rates for Carriage of Agriculture Cargoes on U.S.-Flag Commercial Vessels, 54860
Mariner Cadet Training-Agreements, Compliance Reporting, and Audits, 54859–54860

National Highway Traffic Safety Administration

PROPOSED RULES

Event Data Recorders, 54619–54633

NOTICES

Petition for Decision of Inconsequential Noncompliance:
Continental Tire the Americas, LLC, 54867–54868
Ford Motor Co., 54869–54871
Michelin North America, Inc., 54860–54862, 54864–54865, 54868–54869
ST Engineering Hackney, Inc., 54865–54866
Tesla, Inc., 54871–54873
Vee Rubber Corporation Ltd. and American Honda Motor Co., Inc., 54862–54864

National Indian Gaming Commission

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 54739–54742

National Institutes of Health

NOTICES

Hearings, Meetings, Proceedings, etc.:
Center for Scientific Review, 54699–54721

Nuclear Regulatory Commission**NOTICES**

Environmental Assessments; Availability, etc.:

SHINE Technologies, LLC; SHINE Medical Isotope
Production Facility, 54766–54768

Permits; Applications, Issuances, etc.:

Atomic Alchemy Operators LLC, VIPR Idaho LLC, 54765–
54766

Patent and Trademark Office**NOTICES**

Grant of Interim Extension:

Term of U.S. Patent No. 8,785,125; the Aptima HPV
Assay with the Panther System, 54636

Guidance:

AI-Assisted Inventions, 54636–54637

Pipeline and Hazardous Materials Safety Administration**NOTICES**

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

Pipeline Safety, 54873–54876

Presidential Documents**EXECUTIVE ORDERS**

Genesis Mission; Launch (EO 14363), 55035–55039

Muslim Brotherhood; Designation of Certain Chapters as
Foreign Terrorist Organizations and Specially

Designated Global Terrorists (EO 14362), 55031–55034

Public Buildings Reform Board**NOTICES**

Hearings, Meetings, Proceedings, etc., 54768–54769

Science and Technology Policy Office**NOTICES**

Request for Information:

National Strategic Plan for Advanced Manufacturing,
54769

Securities and Exchange Commission**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 54791–54792, 54814–
54815, 54828–54829, 54832–54833

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

Form S–11–Registration Statement, 54806

Form S–8–Securities Act Registration Statement, 54811–
54812

Meetings; Sunshine Act, 54814

Self-Regulatory Organizations; Proposed Rule Changes:

Cboe BZX Exchange, Inc., 54796–54806, 54833–54837

Cboe Exchange, Inc., 54806–54811

Fixed Income Clearing Corp., 54815–54818

MEMX LLC, 54794–54796

National Securities Clearing Corp., 54792–54794

NYSE Arca, Inc., 54769–54781, 54818–54828

NYSE National, Inc., 54829–54832

The Depository Trust Co., 54812–54814

The Nasdaq Stock Market LLC, 54781–54791

Surface Mining Reclamation and Enforcement Office**RULES**

Applicability of Federal Regulations Implementing the
Surface Mining Control and Reclamation Act, 54571–
54573

Backfilling and Grading, 54573–54575

Certification and Noncoal Reclamation, 54583–54585

General Reclamation Requirements, 54582–54583

Permanent Program Performance Standards Related to
Siltation Structures, 54575–54577

Rescission of Fee Rates, 54579–54581

Rescission of Portions of Permanent Program Performance

Standards Regulating Subsidence Controls for

Underground Mines, 54577–54579

Surface Transportation Board**NOTICES**

Exemption:

Lease and Operation Including Interchange Commitment;
Arkansas Midland Railroad Co., Inc.; Union Pacific
Railroad Co., 54838–54839

Operation; Providence and Worcester Railroad Co.; State
of Connecticut, 54837–54838

Transportation Department

See Federal Aviation Administration

See Federal Motor Carrier Safety Administration

See Maritime Administration

See National Highway Traffic Safety Administration

See Pipeline and Hazardous Materials Safety
Administration

NOTICES

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

Advisory Committee Candidate Biographical Information
Request Form, 54876–54877

Nondiscrimination on the Basis of Disability in Air

Travel: Reporting Requirements for Disability-Related
Complaints, 54880–54882

Privacy Act; Systems of Records, 54877–54880

Treasury Department

See Comptroller of the Currency

See Fiscal Service

See Internal Revenue Service

U.S. Citizenship and Immigration Services**NOTICES**

Temporary Protected Status:

Haiti, 54733–54739

U.S. International Development Finance Corporation**NOTICES**

Hearings, Meetings, Proceedings, etc., 54645

Unified Carrier Registration Plan**NOTICES**

Meetings; Sunshine Act, 54891–54892

Veterans Affairs Department**NOTICES**

Enhanced-Use Lease:

Real Property for the Development of Permanent
Supportive Housing at the Kerrville Veterans Affairs
Medical Center, Kerrville, Texas Campus, 54892

Separate Parts In This Issue**Part II**

Health and Human Services Department, Centers for
Medicare & Medicaid Services, 54894–55030

Part III

Presidential Documents, 55031–55039

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.

3 CFR**Executive Orders:**

14362.....55033
14363.....55035

7 CFR

400.....54523
407.....54523
457.....54523

12 CFR

328.....54544

14 CFR

39 (7 documents) 54545,
54549, 54552, 54555, 54559,
54563, 54568

Proposed Rules:

39 (5 documents) 54591,
54593, 54596, 54599, 54601

21 CFR**Proposed Rules:**

730.....54603

26 CFR**Proposed Rules:**

1.....54604

30 CFR

700.....54571
816 (2 documents) 54573,
54575
817 (2 documents) 54575,
54577
870.....54579
874.....54582
875.....54583

37 CFR

381.....54585

40 CFR

52.....54586
423.....54588

Proposed Rules:

52 (3 documents) 54605,
54607, 54609
70.....54605
257.....54611

42 CFR

405.....54589
410.....54589
414.....54589
424.....54589
425.....54589
427.....54589
428.....54589
495.....54589
512.....54589

Proposed Rules:

422.....54894
423.....54894

49 CFR**Proposed Rules:**

563.....54619
585.....54619

Rules and Regulations

Federal Register

Vol. 90, No. 227

Friday, November 28, 2025

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 AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Parts 400, 407, and 457

[Docket ID FCIC–25–0068]

RIN 0563–AC89

Expanding Access to Risk Protection (EARP)

AGENCY: Federal Crop Insurance Corporation, U.S. Department of Agriculture (USDA).

ACTION: Final rule with request for comments.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) is amending its regulations to implement changes required by the One Big Beautiful Bill Act and to update, streamline, and clarify several crop insurance policies. The changes include clarifying the harvest price methodology, deregulating regionalized program dates and moving that information to the Special Provisions, removing regulatory barriers to direct marketing, incorporating quality adjustment and claims processes, updating FCIC contact information used to request interpretations of policy, and making plain language clarifications and corrections to Subpart X—Interpretations of Statutory Provisions, Policy Provisions, and Procedures; the Area Risk Protection Insurance, Basic Provisions; the Common Crop Insurance Policy, Basic Provisions; and several Crop Provisions. In addition, the changes include removing buy-up coverage for prevented planting in the crop insurance program. The changes will be effective for the 2026 and succeeding crop years for crops with a contract change date on or after November 30, 2025. For all other crops, the changes to the policies made in this rule are applicable for the 2027 and succeeding crop years.

DATES:

Effective date: This final rule is effective November 30, 2025.

Comment Date: FCIC will accept comments on this rule until close of business January 27, 2026. FCIC may consider the comments received and may conduct additional rulemaking based on the comments.

ADDRESSES: We invite you to submit comments on this rule. You may submit comments by going through the Federal eRulemaking Portal as follows:

- **Federal eRulemaking Portal:** Go to <https://www.regulations.gov> and search for Docket ID FCIC–25–0068. Follow the instructions for submitting comments.

All comments received will be posted without change and will be publicly available on <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Chandra Place; telephone: (816) 926–3875; email: chandra.place@usda.gov. Individuals with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice and text telephone (TTY mode)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
- II. Basic Provisions Changes: Area Risk Protection Insurance (ARPI) and Common Crop Insurance Policy (CCIP)
 - A. One Big Beautiful Bill Act Implementation
 - B. Harvest Prices for Revenue Protection
 - C. Production Reporting When the AIP Is Changing
 - D. Reducing Administrative Burden Regarding Prevented Planting
 - E. Written Agreement Deadline Clarification
 - F. Unit Eligibility Clarification
 - G. Definitions
 - H. Duplicative Provisions
- III. Dispute Resolution Changes: Subpart X—Interpretations of Statutory Provisions, Policy Provisions, and Procedures; Area Risk Protection Insurance (ARPI), Basic Provisions; and Common Crop Insurance Policy (CCIP), Basic Provisions
- IV. Crop Provisions Changes
 - A. Deregulating Dates
 - B. Direct Marketing
 - C. Cotton
 - D. Sugar Beets
 - E. Safflower
 - F. Fresh Market Tomatoes Guaranteed Production Plan

- G. Green Pea
- H. Fresh Market Tomato Dollar Plan
- I. Fresh Market Pepper
- J. Forage Seeding
- K. Canola and Rapeseed
- V. Clarifications and Corrections
- VI. Removal of Buy-Up Coverage on Prevented Planting
- VII. Regulatory Analyses
 - A. Notice and Comment and Effective Date
 - B. Executive Orders 12866, 13563, and 14192
 - C. Environmental Review
 - D. Executive Order 13175
 - E. Unfunded Mandates Reform Act
 - F. Paperwork Reduction Act Requirements
 - G. E-Government Act Compliance

I. Background

FCIC serves America's agricultural producers through effective, market-based risk management tools to strengthen the economic stability of agricultural producers and rural communities. FCIC is committed to increasing the availability and effectiveness of Federal crop insurance as a risk management tool. Approved Insurance Providers (AIPs) sell and service Federal crop insurance policies in every state through a public-private partnership. FCIC reinsures the AIPs who share the risks associated with catastrophic losses. FCIC's vision is to secure the future of agriculture by providing world-class risk management tools to rural America.

Federal crop insurance policies typically consist of the Basic Provisions, the Crop Provisions, the Special Provisions, the Commodity Exchange Price Provisions (CEPP), if applicable, other applicable endorsements or options, the actuarial documents for the insured agricultural commodity, the Catastrophic Risk Protection Endorsement, if applicable, and the applicable regulations published in 7 CFR chapter IV.

The Basic Provisions provide underlying policy terms and conditions applicable to many insurable commodities. Specifically, the Area Risk Protection Insurance (ARPI) Basic Provisions apply to policies with area-based coverage, typically established at the county level, and the Common Crop Insurance Policy (CCIP) Basic Provisions apply to policies that provide individualized coverage. Where the terms and conditions are the same, FCIC changes both the ARPI and CCIP Basic Provisions in this rule. The Crop Provisions identify which Basic

Provisions are applicable and establish specific provisions of insurance for each insurable commodity. The Special Provisions and actuarial documents establish county-level provisions for each insurable commodity.

Administrative regulations published in 7 CFR chapter IV apply to the entire Federal Crop Insurance Program. Subpart X is the administrative regulation that provides a mechanism for requesting interpretations of crop insurance policies and procedures.

FCIC is amending the following regulations:

- Subpart X—Interpretations of Statutory Provisions, Policy Provisions, and Procedures (7 CFR 400.765–768);
- Area Risk Protection Insurance Regulations (7 CFR part 407);
- Common Crop Insurance Regulations (7 CFR part 457);
- Cotton crop insurance provisions (7 CFR 457.104);
- Sugar beet crop insurance provisions (7 CFR 457.109);
- Safflower crop insurance provisions (7 CFR 457.125);
- Guaranteed production plan of fresh market tomato crop insurance provisions (7 CFR 457.128);
- Green pea crop insurance provisions (7 CFR 457.137);
- Fresh market tomato (dollar plan) crop insurance provisions (7 CFR 457.139);
- Fresh market pepper crop insurance provisions (7 CFR 457.148);
- Forage seeding crop insurance provisions (7 CFR 457.151); and
- Canola and rapeseed crop insurance provisions (7 CFR 457.161).

Definitions specific to Subpart X are located in 7 CFR 400.765, definitions specific to the ARPI Basic Provisions and corresponding Crop Provisions are located in 7 CFR 407.9, and definitions specific to the CCIP Basic Provisions and corresponding Crop Provisions are located in 7 CFR 457.8. Throughout this rule, the terms “Crop Provisions,” “Special Provisions,” and “policy” are used as defined in the CCIP Basic Provisions in 7 CFR 457.8.

The changes to crop insurance policies resulting from the amendments in this rule are applicable for the 2026 and succeeding crop years for crops with a contract change date on or after November 30, 2025. For all other crops, the changes to the crop insurance policies resulting from the amendments in this rule are applicable for the 2027 and succeeding crop years.

II. Basic Provisions Changes: Area Risk Protection Insurance (ARPI) and Common Crop Insurance Policy (CCIP)

The changes to the Basic Provisions are described below, with important

changes impacting both the ARPI and CCIP Basic Provisions discussed first, followed by changes impacting only the CCIP Basic Provisions, and clarifications and corrections last.

A. One Big Beautiful Bill Act Implementation

On July 4, 2025, President Trump signed into law H.R. 1 (Pub. L. 119–21), also known as the One Big Beautiful Bill Act (OBBBA). FCIC is amending the Area Risk Protection Insurance Regulations (7 CFR 407) by revising the ARPI Basic Provisions as shown in 7 CFR 407.9 and the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8, to implement changes to the Federal Crop Insurance Act made by OBBBA. These changes to the Federal Crop Insurance Act include expanding benefits for beginning farmers and ranchers. The Risk Management Agency (RMA) is also implementing section 10501 (Beginning Farmer and Rancher Benefit) of OBBBA in Manager’s Bulletin MGR–25–006 with an amendment to the CCIP and ARPI Basic Provisions.

For up to 10 crop years, beginning farmers or ranchers will receive an additional 5 percentage point premium subsidy for the first two crop years, an additional 3 percentage point premium subsidy the third crop year, and an additional 1 percentage point premium subsidy the fourth crop year. Thus, when considering the existing beginning farmer or rancher benefits as well as the additional beginning farmer or rancher benefits provided by OBBBA, beginning farmers or ranchers will be eligible to receive a total additional premium subsidy of 15 percentage points in the first two crop years, 13 percentage points in the third crop year, 11 percentage points in the fourth crop year, and 10 percentage points in the fifth through tenth crop years, as opposed to receiving a flat 10 percentage points of additional premium subsidy for 5 years under previous policy.

In this rule, FCIC is revising the definition of “beginning farmer or rancher” in section 1 of the CCIP Basic Provisions and section 1 of the ARPI Basic Provisions to increase the eligibility period of a beginning farmer or rancher who has not actively operated and managed a farm or ranch in any State, with an insurable interest in a crop or livestock as an owner-operator, landlord, tenant, or sharecropper, from 5 crop years to 10 crop years. FCIC is also revising section 7(h) of the ARPI Basic Provisions and 7(g) of the CCIP Basic Provisions to add

the descriptive heading, “Additional premium subsidy”.

B. Harvest Prices for Revenue Protection

FCIC is amending the Area Risk Protection Insurance Regulations (7 CFR 407) by revising the ARPI Basic Provisions as shown in 7 CFR 407.9 and the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8, to clarify that for revenue protection coverage, the harvest price will be set equal to the projected price when data are not available to follow the approved methodology. Projected price and harvest price are defined in section 1 of the ARPI Basic Provisions and section 1 of the CCIP Basic Provisions, and they are determined in accordance with the CEPP.

With revenue protection coverage, a policyholder is eligible for an indemnity payment when there is a revenue loss, such as when the harvest price is less than the projected price (minus the applicable deductible). The projected price is typically established prior to the growing season with data available before planting begins and the harvest price is established during the harvest and delivery period. The approved methodology and data sources for determining the projected and harvest prices are included in the policy (specifically, in the CEPP) provided to producers prior to their deadline for purchasing insurance, so producers can make informed decisions about their coverage. The policy previously specified that if the harvest price cannot be calculated according to the CEPP, the harvest price “will be determined and announced by FCIC.” This phrase did not provide producers with advance notice about how the harvest price would be determined if the price cannot be calculated following the approved methodology.

In this rule, FCIC is establishing in section 12(d) of the ARPI Basic Provisions and section 3(c)(5)(ii) of the CCIP Basic Provisions that, if data are not available to follow the approved methodology, the harvest price will be set equal to the projected price, essentially removing revenue coverage, and the policyholder’s premium will be updated and refunded, as applicable, as if they had purchased yield protection. With these changes, producers will have assurance that they will receive the protection they pay for, even if data do not support revenue coverage at the time of harvest.

C. Production Reporting When the AIP Is Changing

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8, in section 3(f)(1)(ii) to add an exception so that policyholders who transfer their policy to a new AIP for the upcoming year do not need to provide end of year production reporting to the current (and soon-to-be prior) AIP if they do not have a claim. This change provides procedural relief made at the request of stakeholders. Previously, the policy required the policyholder to report their current crop year's production to their current AIP, even if they had transferred their policy to a new AIP for the upcoming year. Concerns were raised that once a policyholder initiates a transfer to a new AIP, both the policyholder and current AIP would prefer to end the business relationship and allow the new AIP to be responsible for administering the production report. Undoing the requirement to continue to report to the current AIP prevents against potential retribution by the Agent the producer has severed ties with. This change to allow policyholders to revert to reporting prior year production information to the new AIP only and not requiring the new AIP to provide production information to the ceding AIP was developed to address concerns and feedback from AIPs, agents, and policyholders in multiple conferences, meetings, and individual requests for relief. This is an added protection for the producer participating in crop insurance. Production reporting for claims purposes and any audit is unchanged and will continue with the current (and soon-to-be prior) AIP for the current year.

D. Reducing Administrative Burden Regarding Prevented Planting

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8 to remove an overly burdensome administrative requirement to verify that the acreage was insured in the past based on the "1 in 4" rule regarding prevented planting payments.

For a policyholder to be eligible for a prevented planting payment, the CCIP Basic Provisions require that the acreage must be physically available for planting. The "1 in 4" rule is one part of the eligibility requirement to prove that the acreage is physically available for planting. Previously, the "1 in 4" rule required that in at least 1 out of the

previous 4 years the acreage must have been:

1. Planted to a crop;
2. Insured; and
3. Harvested, or if not harvested,

adjusted for claim purposes due to an insured cause of loss (other than a cause of loss related to flood, excess moisture, drought, or other cause of loss specified in the Special Provisions).

The specific requirement that the acreage had been "insured" presented substantial challenges to AIPs and producers. If the same operator maintains control of the acreage, proving insurance history on the acreage was relatively simple. However, it was difficult to prove that the acreage had been insured for beginning farmers or ranchers or in any case where the operator for the acreage changed in the previous 4 years.

FCIC is removing the requirement that the acreage had been insured in section 17(f)(8)(i)(E)(2) and 17(f)(8)(ii) of the CCIP Basic Provisions to relieve producers and AIPs of the administrative burden of verifying insurance history while maintaining program integrity by continuing verification of planted and harvested history. All other eligibility requirements to prove that the acreage is physically available for planting remain the same.

E. Written Agreement Deadline Clarification

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8, to clarify the deadline for submitting written agreement requests for insuring a crop in a county that does not currently offer the policy (often known as an XC written agreement). Typically, the deadline for submitting written agreement requests is the cancellation date for the crop policy being requested. In counties where the crop policy is not available, the cancellation date is not always known or as appropriate as it might be due to agronomic differences across locations. Prior to this rule, the CCIP Basic Provisions were confusing and unnecessarily restrictive in terms of what crops could be used as a proxy. For example, if the Crop Provisions specify a cancellation date for "all other states," that cancellation date may not be appropriate for the crop in the county requested by the written agreement. The same crop in a nearby state could be a better proxy for the deadline.

FCIC is clarifying that section 18(e)(2)(ii) of the CCIP Basic Provisions applies when neither the Crop Provisions, nor the Special Provisions,

provide a cancellation date for the county. FCIC is also clarifying that the cancellation date for the requested crop or other insurable crops with similar agronomic conditions may be used as the written agreement deadline, regardless of whether that crop is located in the same state.

F. Unit Eligibility Clarification

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8, to clarify enterprise unit eligibility in section 34(a)(2)(i) and (ii) and to add the descriptive heading, "Whole Farm Unit" to 34(a)(3) of the CCIP Basic Provisions. Previously, the CCIP Basic Provisions stated that the acreage was eligible for enterprise units if the criteria establishing "the basis for" optional units were met (for example, the acreage was located in two or more sections, if "sections are the basis for optional units"). Use of the phrase "basis for" could be inferred to mean that the policyholder had to elect optional units based on that criteria, which is an incorrect interpretation. In order to be used for enterprise unit eligibility, optional units must only be "available by" that criteria.

FCIC is revising the CCIP Basic Provisions so that the regulation uses consistent language with the Crop Insurance Handbook to avoid any potential confusion regarding "the basis" for a requirement to have optional units established in order to qualify for enterprise units, when actually the policyholder is only required to have optional units available to qualify for enterprise units. This rule confirms a clarification that FCIC previously issued in the FCIC 18010 Crop Insurance Handbook, which states that the eligibility for enterprise units relies upon the availability of optional units where the insured acreage is located.

G. Definitions

FCIC is amending the Area Risk Protection Insurance Regulations (7 CFR 407) by revising the ARPI Basic Provisions as shown in 7 CFR 407.9 and the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8, to clarify and add definitions.

FCIC is clarifying the definition of "application" in section 1 of the CCIP Basic Provisions by moving cancellation and termination requirements to section 2 (Life of Policy, Cancellation, and Termination). Previously, the definition of "application" in section 1 of the CCIP

Basic Provisions included requirements for submitting a new application when a policy is cancelled or terminated. These requirements are more appropriately included in section 2(f)(4) of the CCIP Basic Provisions to match how the requirements are specified in the equivalent section of the ARPI Basic Provisions. Relocating the requirements provides greater clarity and transparency, while the requirements remain unchanged.

FCIC is clarifying the definition of “cancellation date” in section 1 of the CCIP Basic Provisions and section 1 of the ARPI Basic Provisions. Prior to this rule, the definition of “cancellation date” only indicated that termination was a reason that a policy would not continue for a subsequent year. FCIC is amending the definition to add the term “or voided” to show that voidance is also a reason that a policy would not automatically continue for a subsequent year. Additional information on cancellation and termination is available in section 2 of the ARPI Basic Provisions in 7 CFR 407.9 and section 2 of the CCIP Basic Provisions in 7 CFR 457.8.

FCIC is adding definitions for “cancellation” and “termination” in section 1 of the ARPI Basic Provisions in 7 CFR 407.9 and section 1 of the CCIP Basic Provisions in 7 CFR 457.8 to provide a clear definition of the words used throughout the regulations. “Void” is already defined in Section 1 of the ARPI Basic Provisions in 7 CFR 407.9 and section 1 of the CCIP Basic Provisions in 7 CFR 457.8.

H. Duplicative Provisions

FCIC is amending the Area Risk Protection Insurance Regulations (7 CFR 407) and the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 407.2 and 7 CFR 457.2 to remove duplicative provisions. Specifically, FCIC is removing paragraph (d) from 407.2 and paragraph (d) from 457.2 and redesignating subsequent paragraphs in both parts. Both removed paragraphs included requirements and instructions on which policy remains active and which policy is void if duplicate policies are found. Provisions addressing duplicate policies were already included in 18(b) of the ARPI Basic Provisions and section 22(a) of the CCIP Basic Provisions. The duplicative language is unnecessary and therefore removed from 7 CFR 407.2 and 7 CFR 457.2.

III. Dispute Resolution Changes: Subpart X—Interpretations of Statutory Provisions, Policy Provisions, and Procedures; Area Risk Protection Insurance (ARPI), Basic Provisions; and Common Crop Insurance Policy (CCIP), Basic Provisions

FCIC is amending Subpart X—Interpretations of Statutory Provisions, Policy Provisions, and Procedures (7 CFR 400.765–768); Area Risk Protection Insurance Regulations (7 CFR 407) by revising the ARPI Basic Provisions as shown in 7 CFR 407.9; and the Common Crop Insurance Regulations (7 CFR part 457) by revising the CCIP Basic Provisions as shown in 7 CFR 457.8, to clarify what happens if an FCIC interpretation or final agency determination is not requested or followed during a dispute.

In accordance with Executive Order 14192, Unleashing Prosperity Through Deregulation, this rule reduces regulatory and administrative burdens during dispute resolution between policyholders and AIPs by clarifying FCIC’s role and removing ambiguity about the Federal Arbitration Act (FAA) (9 U.S.C. 10 and 11).

The Federal Crop Insurance Act requires FCIC to interpret Federal crop insurance policy provisions (7 U.S.C. 1506(r)). Subpart X establishes FCIC’s requirements for the public to request such interpretations and FCIC’s process for responding to such requests in the form of a “final agency determination” for codified provisions or an “FCIC interpretation” for non-codified provisions. These terms are defined in 7 CFR 400.765.

The “automatic nullification” rule contained in Subpart X exceeds the statutory authority provided in the Federal Crop Insurance Act and places FCIC in the role of overruling arbitration awards if either the policyholder or AIP believes that the arbitrator or judge did not adhere to FCIC’s interpretation in their decision. While the Basic Provisions allow an aggrieved party to seek nullification of a failed arbitration, the FAA provides the sole statutory framework for vacating arbitration awards. The FAA authority is usurped, and finality of arbitration is compromised, when parties can use the policy interpretation process to nullify awards with the automatic nullification rule. Rescinding the “automatic nullification” rule reduces administrative and regulatory obstacles to policyholders and their AIPs in finalizing a dispute through the courts. Therefore, in 7 CFR 400.766 and 400.767, sections 20(a) and (c) of the CCIP Basic Provisions, and section 23(d)

of the ARPI Basic Provisions, FCIC is revising the provisions so that arbitration awards can only be challenged in accordance with the FAA. In addition, FCIC is clarifying the authority of the arbitrator. An arbitrator does not have the authority to interpret the policy or FCIC procedure. Further, an arbitrator does not have the authority to disregard or fail to comply with an FCIC interpretation or final agency determination issued in accordance with 7 CFR part 400, subpart X.

In addition, FCIC is adding a definition of “FAA” in the ARPI Basic Provisions and CCIP Basic Provisions and updating the ways to submit a request for a final agency determination and FCIC interpretations by revising the mailing address and deleting the facsimile number in 7 CFR 400.767.

IV. Crop Provisions Changes

FCIC is amending several Crop Provisions as described in the sections below. For specific changes that FCIC is making in more than one Crop Provision, the context and justification for the change is provided under a descriptive sub-heading for that change. Under each Crop Provision where the change appears, FCIC lists the descriptive sub-heading. For changes that FCIC is making in a single Crop Provision, the change is described only under its respective Crop Provision sub-heading.

A. Deregulating Dates

FCIC is amending certain Crop Provisions to relocate contract change dates, end of insurance period (EOIP) dates, cancellation dates, and termination dates to the Special Provisions in cases where there are regional differences in insurance coverage across the country. The Special Provisions are the part of the policy that provide county-level policy provisions, compared to the Crop Provisions which are generalized for the crop anywhere it is grown and insured. These dates are already published in the Special Provisions for each crop and county where insurance is available. Maintaining a separate list of these dates in the regulations is duplicative and can be error-prone. Maintaining these dates only in the Special Provisions allows FCIC to be more responsive and efficient to regional changes in agronomic conditions, technology, or production practices that justify localized date changes specific to an insurable county. Special Provisions are located on the RMA website, and policyholders also receive the Special Provisions for their county with their policy. This change will make it easier for policyholders to

quickly find relevant dates in the Special Provisions without having to sort through program dates that are irrelevant to their county.

B. Direct Marketing

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.139, Fresh Market Tomato (Dollar Plan) Crop Insurance Provisions and 7 CFR 457.148, Fresh Market Pepper Crop Insurance Provisions to allow direct marketing.

This change removes barriers to crop insurance for specialty crop producers who directly market their crops. FCIC conducted a review of specialty crops to identify any crop insurance restrictions on producers' ability to engage in direct marketing. Restrictions were identified for two specialty crops, fresh market tomatoes and fresh market peppers, where the Crop Provisions prohibited insurance for these two commodities if producers sell them directly to consumers.

FCIC is revising the Crop Provisions to allow Special Provisions authorizing insurance in certain locations for fresh market tomatoes and peppers sold directly to consumers. This change allows FCIC to assess local market conditions to identify specific areas where insurance could be offered in the future for tomatoes and peppers sold for direct marketing.

C. Cotton

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.104, Cotton Crop Insurance Provisions, to move cancellation dates, termination dates, and EOIP dates to the Special Provisions, as explained in the "Deregulating Dates" paragraph above, and to incorporate a Special Provisions statement regarding quality adjustment into section 10 (Settlement of Claim) of the Crop Provisions. This rule does not change the quality adjustment or claims process that has been in place since the 2018 crop year, but rather, moves the quality adjustment calculation to the Crop Provisions.

Adverse weather conditions impacting cotton producers in the Southeast in 2015 and 2016 resulted in complaints that FCIC's cotton quality adjustment did not meet the needs of producers. This led to a request for FCIC to consider alternative methods for adjusting poor quality cotton, and in response, FCIC examined data and quality loss procedures in other existing policies with similar quality adjustment provisions to determine an appropriate change. Working with grower groups, FCIC considered alternatives and

increased the 85 percent price threshold (as described in section 10(d)(1)–(3)) to 90 percent and removed the 85 percent deductible. FCIC implemented this change using Special Provisions for the 2018 crop year and this rule incorporates the change into the Crop Provisions, minimizing the need to include the information in multiple locations.

FCIC is also making the following corrections and clarifications in the Cotton Crop Provisions (7 CFR 457.104):

- Removing the phrase "for determining indemnities" from the section heading for section 2. The section heading will now read "Insurance Guarantees, Coverage, Levels, and Prices." The new section heading is more accurate because insurance guarantees, coverage levels, and prices are not exclusively used for determining indemnities. This change is also consistent with section headings of the same name in other Crop Provisions;
- Correcting the misspelling of the word "measures" in section 8(d); and
- Replacing the word "subsection" with "section" in section 10(c)(1)(iii).

D. Sugar Beets

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.109, Sugar Beet Crop Insurance Provisions to move the cancellation and termination dates to the Special Provisions, as explained in the "Deregulating Dates" paragraph above, and to make the following corrections and clarifications:

- Removing the definition of "crop year" from the Crop Provisions because it is duplicative of the same definition in the CCIP Basic Provisions;
- Correcting paragraph references in section 2 and 14(c); and
- Correcting the limit on adjusted production to apply to the applicable Actual Production History (APH) database when the early harvest adjustment option is elected by the policyholder. The early harvest adjustment has a cap (or limit) on the amount the yield may be increased that is designed to ensure that policyholders' APH guarantees are not inflated. Previously, section 18(b)(5) based the limit on the approved yield for the unit. For sugar beets, the unit is the insurable acreage of the sugar beets used to establish the production guarantee, premium, and indemnity. However, units are not the appropriate basis for the yield limit, because a single approved yield may not be calculated for a unit, which may contain multiple types and practices. The most appropriate methodology for establishing the limit is the approved

yield from the applicable APH database for each insurable type and practice. FCIC previously issued a procedural correction revising the yield limit to use the applicable APH database. FCIC is revising the Crop Provisions to align with the procedural correction.

E. Safflower

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.125, Safflower Crop Insurance Provisions by moving the contract change date from December 31 to November 30 in section 3 to match other spring crops to improve administrative efficiency for AIPs, agents, and the FCIC.

As explained in the "Deregulating Dates" paragraph above, FCIC is moving cancellation and termination dates to the Special Provisions.

FCIC added an example immediately following section 11(b) in the Settlement of Claim section to show how an indemnity is calculated to be consistent with other Crop Provisions.

FCIC is also making the following corrections and clarifications in the Safflower Crop Insurance Provisions (7 CFR 457.125):

- Removing the definition of "nurse crop (companion crop)" in section 1 as this term is not used in the Crop Provisions;
- Replacing the phrase "agree in writing" in section 6(a) with the defined term "written agreement." "Written agreement" is specifically defined in the CCIP Basic Provisions. The use of "agree in writing" was intended to mean that the producer must have a written agreement;
- Removing a duplicate listing of replanting payment factors from section 9(b). The replant payment factors are also included in the policy in the actuarial documents. Keeping the replanting payment factors in the actuarial documents, without duplicating the factors in the regulation, improves administrative efficiency and reduces errors in updating the payment factors in the future; and
- Removing section 11(d)(3)(ii) and renumbering subsequent paragraphs as there was a Special Provisions statement excluding this provision, making it obsolete. Upon removing 11(d)(3)(ii), that portion of the Special Provisions statement will also be removed.

F. Fresh Market Tomatoes Guaranteed Production Plan

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.128, Guaranteed Production Plan of Fresh Market Tomato Crop Insurance Provisions to

move the cancellation dates, termination dates, and the EOIP date to the Special Provisions along with extending the EOIP date for Tennessee, extending the cancellation and termination dates for South Carolina by approximately 45 days, and updating insurable types of tomatoes to include “grape” types.

As explained in the “Deregulating Dates” paragraph above, FCIC is moving the cancellation dates, termination dates, and the EOIP date to the Special Provisions. Upon moving these dates to the Special Provisions, FCIC is extending the EOIP date for Tennessee from September 20 to October 15 and extending the cancellation and termination dates for South Carolina by approximately 45 days. Extending insurance in Tennessee protects producers from hurricanes in late September and early October, when there is still a small portion of the liability remaining in the field. By revising the cancellation and termination dates for South Carolina, FCIC is effectively extending the sales period by approximately 45 days. This change aligns the sales period for South Carolina with neighboring counties in North Carolina, providing additional time for producers to purchase insurance, and reducing confusion for producers and AIPs who operate in both South Carolina and North Carolina.

FCIC is adding the “grape” type of tomatoes to the Crop Provisions. Adding the “grape” type of tomato to the Crop Provisions adds clarity to the policy because this type is already insurable through the Special Provisions.

FCIC is also making the following corrections and clarifications in the Fresh Market Tomato Production Guaranteed Plan Crop Provisions (7 CFR 457.128):

- Clarifying the availability of optional units by establishing an exhaustive list of the criteria by which an optional unit may and may not be established in section 2(b); and
- Removing a duplicate listing of replanting payment factors from section 12(b). The replant payment factors are also included in the policy in the actuarial documents. Keeping the replanting payment factors in the actuarial documents, without duplicating them in the regulation, improves administrative efficiency and reduces errors in updating the factors in the future.

G. Green Pea

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.137, Green Pea Crop Insurance Provisions, to move

cancellation and termination dates to the Special Provisions, as explained in the “Deregulating Dates” paragraph above and to make the following corrections and clarifications:

- Clarifying the definition of “production guarantee (per acre)” to indicate the production guarantee per acre is specified in pounds; and
- Clarifying the availability of optional units by establishing an exhaustive list of the criteria by which an optional unit may and may not be established in section 2(b).

H. Fresh Market Tomato Dollar Plan

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.139, Fresh Market Tomato (Dollar Plan) Crop Insurance Provisions to allow the Special Provisions to provide insurance for production sold through direct marketing, as explained in the “Direct Marketing” paragraph above and moving the cancellation date and termination date to the Special Provisions, as explained in the “Deregulating Dates” paragraph above. FCIC is also making the following corrections and clarifications:

- Clarifying the availability of optional units by establishing an exhaustive list of the criteria by which an optional unit may or may not be established in section 2(b); and
- Correcting the policy location for the replanting payment amount to the actuarial documents, not the Special Provisions.

I. Fresh Market Pepper

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.148, Fresh Market Pepper Crop Insurance Provisions to facilitate crop insurance expansion, particularly to East Coast states, by moving cancellation dates and termination dates to the Special Provisions, as explained in the “Deregulating Dates” paragraph above, and adding a new contract change date reflective of the growing season in certain East Coast states. FCIC is also allowing the Special Provisions to provide insurance for production sold through direct marketing, as described in the “Direct Marketing” paragraph above.

This rule seeks to facilitate crop insurance expansion to additional states, particularly on the East Coast. FCIC is adding a new contract change date in the Crop Provisions and moving the termination dates and cancellation dates to the Special Provisions, where they will be updated on a county basis for future expansions. Previously, crop

insurance for fresh market peppers was only available in southeastern states where peppers have a different growing season than in states further north. Producers, particularly in Northeastern states, have indicated that the previous program dates were a barrier to obtaining crop insurance.

FCIC is also making the following corrections and clarifications in the Fresh Market Pepper Crop Provisions (7 CFR 457.148):

- Clarifying the definition of “crop year” to encompass growing seasons in certain East Coast states. The crop year covers all planting periods shown in the Special Provisions for the county and is identified by the calendar year of harvest for the latest planting period;
- Clarifying the definition of “harvest” so that it only refers to picking peppers that are mature;
- Expanding the definition of “planting period” to include planting in certain East Coast states in the summer season;
- Clarifying the definition of “practical to replant” to show that for fresh market peppers, an AIP may consider crop marketing windows, in addition to the criteria established in the CCIP Basic Provisions, in their determination of whether the crop is practical to replant;
- Clarifying the availability of optional units by establishing an exhaustive list of the criteria by which an optional unit may or may not be established in section 2(b);
- Allowing the EOIP to be modified in the Special Provisions;
- Correcting the policy location for the replanting payment amount to the actuarial documents, not the Special Provisions; and
- Moving the percentage of production to be counted for catastrophic risk protection coverage to the actuarial documents.

J. Forage Seeding

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.151, Forage Seeding Crop Insurance Provisions to move the cancellation and termination dates to the Special Provisions, as explained in the “Deregulating Dates” paragraph above. FCIC is also clarifying the definition of “crop year” to show that it is in lieu of the same definition in the CCIP Basic Provisions.

K. Canola and Rapeseed

FCIC is amending the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.161, Canola and Rapeseed Crop Provisions to move the cancellation and termination dates to

the Special Provisions, as explained in the “Deregulating Dates” paragraph above. FCIC is also making the following corrections and clarifications:

- Changing the phrase “in accordance with” to “by” in the definition of “canola” to show that the genus is “defined by” the Official U.S. Standards for Grain; and
- Removing a duplicate listing of replanting payment amounts from section 10(b). The replant payment amounts are also included in the policy in the actuarial documents. Keeping the replanting payment amounts in the actuarial documents, without duplicating them in the regulation, improves administrative efficiency and reduces errors in updating the amounts in the future.

V. Clarifications and Corrections

Throughout this rule, FCIC is making several corrections and clarifications for plain language and adherence to the Government Printing Office Style Manual. FCIC is providing an overview of these corrections and clarifications here:

- Revising references to “the Corporation” and “Federal Crop Insurance Corporation” to “FCIC” as defined in 7 CFR part 400, the ARPI Basic Provisions, and the CCIP Basic Provisions;
- Reducing redundancy, eliminating potential conflicts, and clarifying definitions that appear in both the Basic Provisions and individual Crop Provisions, by removing duplicative definitions, or adding the phrases “in addition to” or “in lieu of” to applicable definitions within Crop Provisions;
- Clarifying which Basic Provisions apply by adding an introductory sentence preceding the Crop Provisions and updating the effective year within the introductory sentence to show the year to which the changes in the Crop Provisions apply;
- Removing the introductory sentence explaining the order of priority in individual Crop Provisions because it is duplicative of the CCIP Basic Provisions, which already include the priority order of policy provisions;
- To conform with the Government Publishing Office Style Manual:
 - Correcting the capitalization of “states” to “States”;
 - Changing the spelling of numbers to numerals;
 - Correcting “a” to “an” or vice versa preceding an acronym;
 - Correcting punctuation;
 - Removing parentheticals repeating a numerical percentage following a spelled out percentage;

- To improve clarity in writing for plain language:
 - Replacing “herein,” “therein,” and “thereof” with descriptive phrases;
 - Replacing “e.g.” with “for example”;
 - Replacing “in excess of” with “exceeding”;
 - Replacing “in compliance” with “complies”;
 - Removing unnecessary words and phrases, such as “contained in,” and “the provisions of” when referring to regulatory provisions by number;
- Updating crop years in examples with more current years;
- Clarifying the settlement of claim examples in Crop Provisions by clarifying where the example begins and ends, updating prices to be more reflective of current crop prices and potential indemnities, correcting the defined term “production guarantee (per acre)” as applicable, or clarifying which steps of the examples are not applicable;
- Correcting paragraph numbering in definitions;
- Correcting outdated statute references; and
- Removing duplicative provisions.

VI. Removal of Buy-Up Coverage on Prevented Planting

Prevented planting is a de facto coverage in all crop insurance policies. Increased coverage above the basic level, referred to as “buy-up” coverage, is an option that is provided administratively by RMA in annual notifications. Producers that elect buy-up coverage pay a slightly higher premium to qualify for an indemnity payment that is 5 percent more than the basic coverage. However, the buy-up coverage is mainly benefitting farmers in the Dakotas seeking to plant in the Prairie Pothole Region, where the majority of prevented planting crop insurance payments are made. This is no longer needed because Congress has a history of addressing wide-spread flooding through ad-hoc disaster assistance, such as the 2019 Supplemental bill that funded prevented planting “top-off” payments, providing an additional 10 to 15 percent to eligible producers who had already received prevented planting indemnities.

VII. Regulatory Analyses

A. Notice and Comment and Effective Date

The Administrative Procedure Act (APA, 5 U.S.C. 553) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves specified

actions, including matters relating to contracts. This rule governs contracts for crop insurance policies and therefore falls within that exemption.

This rule is exempt from the regulatory analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The exemption under section 553 for matters related to contracts extends to the regulatory analysis requirement for this rule.

The Office of Management and Budget (OMB) found this rule meets the criteria in 5 U.S.C. 804(2) of the Congressional Review Act (CRA). The CRA, at 5 U.S.C. 808(2) allows an agency to make such regulations effective immediately if the agency finds there is good cause to do so. USDA has determined that such good cause exists here because the rule changes relate to matters of a contract. Postponing the effective date of the rule would result in a one-year delay in providing the benefits of the rule to American farmers and ranchers. Therefore, USDA is not required to delay the effective date for 60 days from the date of publication to allow for Congressional review. Accordingly, this rule is effective upon publication in the **Federal Register**.

Therefore, this final rule is effective on November 30, 2025. Although not required by APA or any other law, FCIC has chosen to request comments on this rule.

B. Executive Orders 12866, 13563, and 14192

Executive Order 12866, “Regulatory Planning and Review,” and Executive Order 13563, “Improving Regulation and Regulatory Review,” 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). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 14192 “Unleashing Prosperity Through Deregulation” announced the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen and to alleviate unnecessary regulatory burdens placed on the American people. In line with

the Executive Order requirements, the Agency chose this regulatory approach to harmonize rules and procedures, maximize flexibility, and increase efficiency by alleviating unnecessary regulatory burdens.

The requirements in Executive Orders 12866 and 13563 for the analysis of costs and benefits apply to rules that are determined to be significant or economically significant. This rule has been designated as not significant and therefore, OMB has not reviewed this rule and analysis of the costs and benefits is not required.

C. Environmental Review

The environmental impacts of this final rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), and the USDA regulation for compliance with NEPA (7 CFR part 1b). As specified in 7 CFR parts 1b.3(f) and 1b.4(a)(3), FCIC is categorically excluded from the preparation of an Environmental Assessment or Environmental Impact Statement unless the FCIC Manager (agency head) determines that an action may have a significant environmental effect or an extraordinary circumstance exists. The FCIC Manager has determined this rule will not have a significant environmental effect and no extraordinary circumstances exist. Therefore, FCIC will not prepare an environmental assessment or environmental impact statement for this action and this documents the programmatic environmental compliance finding of applicability and no extraordinary circumstances (FANEC).

D. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

USDA has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that require Tribal consultation at this

time. If a Tribe requests consultation, RMA will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions of State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with Federal mandates that may result in expenditures of \$100 million or more in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in Title II of UMRA, for State, local, and Tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

F. Paperwork Reduction Act Requirements

In accordance with the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, subchapter I), the rule does not change the information collection approved by OMB under control numbers 0563–0053; Expiration Date: 3/31/2026, 0563–0083; Expiration Date: 11/30/2026, and 0563–0055; Expiration Date: 11/30/25 (currently at OMB seeking approval to renew collection). No new information will be collected through this rule. All information has already been collected.

G. E-Government Act Compliance

RMA is committed to complying with the E-Government Act of 2002, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Federal Assistance Program

The title and number of the Assistance Listing, to which this rule applies is No. 10.450—Crop Insurance.

List of Subjects

7 CFR Part 400

Acreage allotments, Administrative practice and procedure, Claims, Crop insurance, Drug traffic control, Fraud, Government employees, Income taxes, Intergovernmental relations, Penalties,

Reporting and recordkeeping requirements, Wages.

7 CFR Part 407

Acreage allotments, Administrative practice and procedure, Barley, Corn, Cotton, Crop insurance, Peanuts, Reporting and recordkeeping requirements, Sorghum, Soybeans, Wheat.

7 CFR Part 457

Acreage allotments, Crop insurance, Reporting and recordkeeping requirements.

Final Rule

For the reasons discussed above, FCIC amends 7 CFR parts 400, 407, and 457, effective for the 2026 and succeeding crop years for crops with a contract change date on or after November 30, 2025, and for the 2027 and succeeding crop years for all other crops, as follows:

PART 400—GENERAL ADMINISTRATIVE REGULATIONS

- 1. The authority citation for part 400 continues to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

Subpart X—Interpretations of Statutory Provisions, Policy Provisions, and Procedures

- 2. Add an authority citation for subpart X to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(o), and 1506(r).

- 3. Amend § 400.765 as follows:

- a. In the definition of “approved insurance provider”, remove the first instance of the word “FCIC” and add “the Federal Crop Insurance Corporation (FCIC)” in its place; and
- b. Add a definition of “FAA” in alphabetical order.

The addition reads as follows:

§ 400.765 Definitions.

* * * * *

FAA. The Federal Arbitration Act found at 9 U.S.C. 1 *et seq.*

* * * * *

- 4. Amend § 400.766 as follows:

- a. Revise paragraph (a);
- b. In paragraphs (b) introductory text and (b)(1) introductory text, remove the words “a FCIC” wherever they appear and add “an FCIC” in their place;
- c. Revise paragraph (b)(1)(i);
- d. Remove paragraphs (b)(3) and (4);
- e. Redesignate paragraphs (b)(5) and (6) as paragraphs (b)(3) and (4);
- f. In newly redesignated paragraph (b)(4) introductory text, remove the words “a FCIC” and add “an FCIC” in their place;

- g. In newly redesignated paragraph (b)(4)(i), remove the words “an administrative review” and add “administrative review” in their place;
- h. In newly redesignated paragraph (b)(4)(iv), remove the words “a FCIC” and add “an FCIC” in their place; and
- i. Add paragraphs (c) and (d).

The revisions and additions read as follows:

§ 400.766 Basis and applicability.

(a) The regulations in this part prescribe the rules and criteria for obtaining a final agency determination or an FCIC interpretation.

(1) FCIC will provide a final agency determination or an FCIC interpretation, as applicable, for statutory, regulatory, or other policy provisions or procedures that were in effect during the 4 most recent crop years from the crop year in which your request was submitted. For example, for a request received in the 2025 crop year, FCIC will consider requests for the 2025, 2024, 2023, and 2022 crop years.

(2) If FCIC determines a request is outside the scope of crop years authorized in paragraph (a)(1) of this section, you will be notified within 30 days of the date of receipt by FCIC.

(3) If the statutory, regulatory, or other policy provisions or procedures have changed for the time period you seek an interpretation you must submit a separate request for each policy provision or procedure by year. For example, if you seek an interpretation of section 6(b) of the Small Grains Crop Provisions for the 2022 through 2025 crop years but the policy provisions were revised starting with the 2024 crop year, you must submit two requests, one for the 2022 and 2023 crop years and another for the 2024 and 2025 crop years.

(b) * * *

(1) * * *

(i) The parties are required to seek an interpretation of the disputed provision from FCIC in accordance with this subpart. (This may require that the parties seek a stay of the proceedings until an interpretation is provided, if such proceedings have been initiated.); and

* * * * *

(c) With respect to the authority of an arbitrator selected to resolve a dispute under any FCIC reinsured policy that involves a disputed policy provision or FCIC procedure:

(i) The arbitrator does not have the authority to interpret policy provisions or FCIC procedure; and

(ii) The arbitrator exceeds their authority if they interpret policy provisions or FCIC procedure or if the

arbitrator disregards or fails to comply with a final agency determination or an FCIC interpretation issued in accordance with this subpart.

(d) The FAA governs any judicial review of an arbitration award involving a policy issued under the authority of the Act.

* * * * *

■ 5. Amend § 400.767 as follows:

- a. Revise paragraph (a)(1);
- b. In paragraph (a)(3), remove the words “a FCIC” and add “an FCIC” in their place;
- c. In paragraph (a)(4), remove the words “interpretation (You” and add “interpretation. (You” in their place, and remove the words “are required);” and add “are required.);” in their place;
- g. In paragraph (b)(1), remove the text “(e.g.,” and add “(for example,” in its place;
- h. Remove paragraph (b)(3)(ii);
- i. Redesignate paragraph (b)(3)(iii) as paragraph (b)(3)(ii);
- j. Revise newly redesignated paragraph (b)(3)(ii);
- k. In paragraph (b)(4), remove the text “; and” and add a period in its place; and
- l. Remove paragraph (b)(5).

The revisions read as follows:

§ 400.767 Requestor obligations.

(a) * * *

(1) Be submitted to the Deputy Administrator using the guidelines provided on RMA’s website at www.rma.usda.gov through one of the following methods:

(i) In writing by certified mail or overnight delivery, to the Deputy Administrator, Risk Management Agency, United States Department of Agriculture, P.O. Box 419205, Kansas City, MO 64141–6205; or

(ii) By electronic mail at subpartx@rma.usda.gov;

* * * * *

(b) * * *

(3) * * *

* * * * *

(ii) Notwithstanding paragraph (b) of this section, if during the mediation, arbitration, or litigation, an issue arises that requires a final agency determination or FCIC interpretation, the mediator, arbitrator, judge, or magistrate must promptly request a final agency determination or FCIC interpretation in accordance with § 400.767(a).

* * * * *

■ 6. Amend § 400.768 as follows:

- a. In paragraph (c), remove the word “sixty” and add “60” in its place;
- b. In paragraph (d), remove the words “a FCIC” and add “an FCIC” in their place;

- c. In paragraphs (e) and (f), remove the words “a FCIC” wherever they appear and add “FCIC” in their place; and
- d. Revise paragraph (i).

The revision reads as follows:

§ 400.768 FCIC obligations.

* * * * *

(i) When issuing a final agency determination or FCIC interpretation, FCIC will not evaluate the insured, insurance provider, agent, or loss adjuster as it relates to their performance in following FCIC policy provisions or procedures. Interpretations will not include any analysis of whether the insured, insurance provider, agent, or loss adjuster complied with the policy provision or procedure in question.

PART 407—AREA RISK PROTECTION INSURANCE REGULATIONS

■ 7. The authority citation for part 407 continues to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

■ 8. Amend § 407.2 as follows:

- a. In paragraph (a) remove the words “Federal Crop Insurance Act (7 U.S.C. 1501–1524) (Act)” and add “Federal Crop Insurance Act (7 U.S.C. 1501–1524), as amended (Act)” in their place;
 - b. In paragraph (b), remove the words “the FCIC” and add “FCIC” in their place;
 - c. Remove paragraph (d); and
 - d. Redesignate paragraphs (e) through (g) as paragraphs (d) through (f).
- 9. In § 407.8, revise paragraph (b).
The revision reads as follows:

§ 407.8 The application and policy.

* * * * *

(b) FCIC or the insurance provider may reject, no longer accept applications, or cancel existing insurance contracts upon FCIC’s determination that the insurance risk is excessive. Such determination must be made not later than 15 days before the cancellation date for the crop and may be made on an area, county, State, or crop basis.

* * * * *

■ 10. Amend § 407.9 as follows:

- a. Remove the text “e.g.” wherever it appears and add “for example” in its place;
- b. In the second paragraph of the “Reinsured Policies” section that precedes Terms and Conditions:
 - 1. Remove the words “the Risk Management Agency (RMA’s)” and add “RMA’s” in their place; and
 - 2. Remove the words “No state” and add “No State” in their place;
- c. In section 1:

- 1. Revise the definition “Beginning farmer or rancher”;
- 2. Add a definition of “Cancellation” in alphabetical order;
- 3. In the definition of “Cancellation date”, remove the words “or terminated” and add “or terminated or voided” in their place;
- 4. In the definition of “Cooperative Extension System”, remove the words “state office located at each state’s land-grant university,” and add “State office located at each State’s land-grant university,” in their place;
- 5. In the definition of “County”, remove the word “state” and add “State” in its place;
- 6. Add a definition of “FAA” in alphabetical order;
- 7. In the definition of “Perennial crop”, remove the word “one” and add “1” in its place;
- 8. In the definition of “Person”, remove the words “agency thereof” and add “government agency” in their place;
- 9. In the definition of “Prohibited substance”, remove the words “organic, transitional or” and add “organic, transitional, or” in their place;
- 10. In the definition of “State”, remove the words “state shown” and add “State shown” in their place;
- 11. In the definition of “Substantial beneficial interest”, remove the words “state dissolution” and add “State dissolution” in their place; and
- 12. Add the definition of “Termination” in alphabetical order;
- d. In section 2:
 - 1. In paragraph (d)(3), remove the words “in excess of” and add “exceeding” in their place;
 - 2. In paragraph (k)(2)(i)(A), remove the words “billing date for the crop year” and add “billing date for the crop year.” in their place;
 - 3. In paragraph (k)(2)(i)(B), remove the words “delinquent debt” and add “delinquent debt.” in their place;
 - 4. Revise paragraph (k)(2)(i)(D);
 - 5. In paragraph (l)(3)(ii), remove the words “or on after” and add “or on or after” in their place; and
 - 6. Revise paragraph (p)(2);
- e. In section 5, in paragraph (c) introductory text, remove the word “states” and add “States” in its place;
- f. In section 7, revise paragraph (h);
- g. In section 12, revise paragraph (d);
- h. In section 13:
 - 1. In paragraph (c)(4), remove the words “two of the last four” wherever they appear and add “2 of the last 4” in their place;
 - 2. In paragraph (d) introductory text, remove the word “four-year” and add “4-year” in its place;
 - 3. In paragraphs (d)(1) and (d)(2), remove the words “two of the last four”

- wherever they appear and add “2 of the last 4” in their place;
 - 4. In paragraph (d)(3)(i), remove the words “2019 and 50 of those acres were double cropped with soybeans; and 100 acres of wheat planted in 2020” and add “2024 and 50 of those acres were double cropped with soybeans; and 100 acres of wheat planted in 2025” in their place;
 - 5. In paragraph (d)(3)(ii), remove the words “2019 and 70 divided by 100 equals 70 percent of the first insured crop acres that were double cropped in 2020” and add “2024 and 70 divided by 100 equals 70 percent of the first insured crop acres that were double cropped in 2025” in their place;
 - 6. In paragraph (d)(3)(iv), remove the year “2021” and add “2026” in its place; and
 - 7. In paragraph (e), remove the words “in excess of” and add “exceeding” in their place;
 - i. In section 21, in paragraphs (b) and (c), remove the word “three” wherever it appears and add “3” in its place;
 - j. In section 23 [FCIC Policies], in paragraph (d)(1), remove the word “one” and add “1” in its place;
 - k. In section 23 [Reinsured Policies]:
 - 1. In paragraphs (b)(2)(ii)(C) and (c), remove the word “one” wherever it appears and add “1” in its place;
 - 2. Revise paragraph (d)(3)(ii) and (d)(4)(ii);
 - 3. In paragraph (d)(5)(ii), remove the words “judicial review” and add “a judicial review as described in section 23(g)” in their place;
 - 4. In paragraph (d)(5)(iii), remove the words “judicial review is sought, suit must be filed not later than one year” and add “a judicial review as described in section 23(g) is sought, suit must be filed not later than 1 year” in their place;
 - 5. Revise paragraph (d)(6);
 - 6. In paragraph (e), remove the word “state” and add “State” in its place; and
 - 7. In paragraph (g), remove the text “SW.” and add “SW” in its place;
 - l. In section 24, in paragraph (b), remove the text “(41 U.S.C. 7611)” and add “(41 U.S.C. 7109)” in its place;
 - m. In section 30, revise Step 9: Calculate the Payment Factor of the *Area Revenue Protection example*; and
 - n. In section 31, remove the period at the end of the section heading;
- The revisions and additions read as follows:
- § 407.9 Area risk protection insurance policy.**
- * * * * *
1. Definitions
- * * * * *
- Beginning farmer or rancher.* An individual who has not actively

operated and managed a farm or ranch in any State, with an insurable interest in a crop or livestock as an owner-operator, landlord, tenant, or sharecropper for more than 10 crop years. An individual’s insurable interest in any crop year may be excluded at the request of the individual if the interest was held by the individual while: (1) under the age of 18; (2) in full-time military service of the United States; or (3) in post-secondary education. A person other than an individual may be eligible for beginning farmer or rancher benefits if there is at least one individual substantial beneficial interest holder and all individual substantial beneficial interest holders qualify as a beginning farmer or rancher.

* * * * *

Cancellation. When the policy is no longer in effect as of the cancellation date.

* * * * *

FAA. The Federal Arbitration Act found at 9 U.S.C. 1 *et seq.*

* * * * *

Termination. When the policy is no longer in effect as of the date specified in the policy.

* * * * *

2. Life of Policy, Cancellation, and Termination

* * * * *

- (k) * * *
- (2) * * *
- (i) * * *

(D) For execution of a written payment agreement and failure to make any scheduled payment, the termination date for the crop year prior to the crop year in which you failed to make the scheduled payment (for this purpose only, the crop year will start the day after the termination date and end on the next termination date, for example, if the termination date is November 30 and you fail to make a payment on November 15, 2025, your policy will terminate on November 30, 2024, for the 2025 crop year).

* * * * *

- (p) * * *

(2) Since applications for crop insurance cannot be accepted after the sales closing date, if you make any payment, or you otherwise become eligible, after the sales closing date, you cannot apply for insurance until the next crop year. For example, for the 2025 crop year, if crop A, with a termination date of October 31, 2024, and crop B, with a termination date of March 15, 2025, are insured and you do not pay the premium for crop A by the termination date, you are ineligible for crop insurance as of October 31, 2024,

and crop A's policy is terminated as of that date. Crop B's policy does not terminate until March 15, 2025, and an indemnity for the 2024 crop year may still be owed. You will not be eligible to apply for crop insurance for any crop until after the amounts owed are paid in full or you have your debts discharged in bankruptcy.

* * * *

7. Annual Premium and Administrative Fees

* * * *

(h) Additional premium subsidy—If you qualify as a beginning farmer or rancher, or veteran farmer or rancher, the premium subsidy that you would otherwise receive will be increased, unless otherwise specified in the Special Provisions. If you qualify as:

(1) A beginning farmer or rancher, your premium subsidy will be increased by:

(i) 15 percentage points for the first through second crop years;

(ii) 13 percentage points for the third crop year;

(iii) 11 percentage points for the fourth crop year; and

(iv) 10 percentage points for the fifth through tenth crop years;

(2) A veteran farmer or rancher, your premium subsidy will be increased by 10 percentage points; or

(3) Both a beginning farmer or rancher and a veteran farmer or rancher, your premium subsidy will equal that of the beginning farmer or rancher, which is equivalent or higher.

* * * *

12. Triggers, Final Policy Protection, Payment Factor, and Indemnity Calculations

* * * *

(d) If the harvest price cannot be calculated for the current crop year under the provisions contained in the CEPP:

(1) Notice will be provided on RMA's website;

(2) The harvest price will equal the projected price; and

(3) Your premium will be recalculated as though you had elected Area Yield Protection. Any premium previously paid exceeding the new amount will be returned to you.

* * * *

[Reinsured policies]

23. Mediation, Arbitration, Appeal, Reconsideration, and Administrative and Judicial Review

* * * *

(d) * * *

(3) * * *

(ii) An arbitrator does not have the authority to:

(A) Interpret the policy or FCIC procedure; or

(B) Disregard or fail to comply with a final agency determination or FCIC interpretation issued in accordance with 7 CFR part 400, subpart X. An arbitration award that is inconsistent with section 23 may be appealed in accordance with the FAA.

* * * *

(4) * * *

(ii) The arbitrator does not have the power to issue an award that does not conform to section 23. Failure of the arbitrator to provide such written statement may be appealed in accordance with the FAA.

* * * *

(6) The FAA governs arbitrations initiated under section 23(d)(5)(i) and any decision rendered in arbitration is binding on you and us unless vacated, modified, or corrected, in accordance with the FAA.

* * * *

30. Examples

* * * *

Area Revenue Protection example:

* * * *

Step 9: Calculate the Payment Factor

Formula: (Trigger revenue minus final county revenue) divided by (trigger revenue minus (expected county yield times the greater of projected or harvest price times loss limit factor)) equals payment factor

$(\$484.65 - \$342.75) \div (\$484.65 - (141.4 \times \$4.57 \times .18)) = .385$ payment factor

* * * *

PART 457—COMMON CROP INSURANCE REGULATIONS

■ 11. The authority citation for part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

■ 12. Amend § 457.2 as follows:

■ a. Revise paragraphs (a) and (b);

■ b. Remove paragraph (d);

■ c. Redesignate paragraphs (e) through (g) as paragraphs (d) through (f); and

■ d. Revise newly redesignated paragraph (e).

The revisions read as follows:

§ 457.2 Availability of Federal crop insurance.

(a) Insurance shall be offered under the provisions of this section on the insured crop in counties within the limits prescribed by and in accordance with the provisions of the Federal Crop Insurance Act (7 U.S.C. 1501–1524), as amended (Act). The crops and counties

shall be designated by the Manager of the Federal Crop Insurance Corporation (FCIC) from those approved by the Board of Directors of FCIC.

(b) The insurance is offered through companies reinsured by FCIC that offer contracts containing the same terms and conditions as the contract set out in this part. These contracts are clearly identified as being reinsured by FCIC. FCIC may offer the contract for the catastrophic level of coverage contained in this part and part 402 of this chapter directly to the insured through local offices of the Department of Agriculture only if the Secretary determines that the availability of local agents is not adequate. Those contracts are specifically identified as being offered by FCIC.

* * * *

(e) An insured whose contract with FCIC or with a company reinsured by FCIC under the Act has been terminated because of violation of the terms of the contract is not eligible to obtain multiple peril crop insurance under the Act with FCIC or with a company reinsured by FCIC unless the insured can show that the default in the prior contract was cured prior to the sales closing date of the contract applied for or unless the insured can show that the termination was improper and should not result in subsequent ineligibility.

* * * *

■ 13. Amend § 457.7, by removing the words “the Corporation” wherever they appear and adding “FCIC” in their place.

■ 14. Amend § 457.8 as follows:

■ a. Remove the text “e.g.” wherever it appears and add “for example” in its place;

■ b. In paragraph (a), remove the words “the Corporation” wherever they appear and add “FCIC” in their place;

■ c. Under the heading “FCIC Policies”, in the second paragraph, remove the words “refer to the Federal Crop Insurance Corporation” and add “refer to FCIC” in their place;

■ d. Under the heading “Reinsured Policies”, in the first paragraph, remove the words “No state” and add “No State” in their place;

■ e. In section 1:

■ 1. In the definition of “APH base period”, remove the words “four, up to a maximum of ten,” and add “4, up to a maximum of 10,” in their place;

■ 2. Revise the definitions of “Application” and “Beginning farmer or rancher”;

■ 3. Add a definition of “Cancellation” in alphabetical order;

■ 4. In the definition of “Cancellation date”, remove the words “or

terminated” and add “or terminated or voided” in their place;

■ 5. In the definition of “Continuous production reports”, remove the word “herein” and add “in this definition” in its place;

■ 6. In the definition of “County”, remove the word “state” and add “State” in its place;

■ 7. Add a definition of “FAA” in alphabetical order;

■ 8. In the definition of “New producer”, remove the word “two” and add “2” in its place;

■ 9. In the definition of “Perennial crop”, remove the word “one” and add “1” in its place;

■ 10. In the definition of “Person”, remove the words “agency thereof” and add “government agency” in their place;

■ 11. In the definition of “Prohibited substance”, remove the words “organic, transitional or” and add “organic, transitional, or” in their place;

■ 12. In the definition of “Replanted crop”, in paragraph (1)(i), remove the words “by the policy and” and add “by the policy, and” in their place;

■ 13. In the definition of “Representative sample”, remove the words “instances we” and add “instances, we” in their place;

■ 14. In the definition of “State”, remove the words “state shown” and add “State shown” in their place; and

■ 15. Add a definition of “Termination” in alphabetical order;

■ f. In section 2:

■ 1. In paragraph (b)(7)(iii), remove the words “in excess of” and add “exceeding” in their place;

■ 2. In paragraph (b)(10) introductory text, remove the words “a SSN or EIN” and add “an SSN or EIN” in their place;

■ 3. In paragraph (f)(1)(ii), remove the words “sections 2(f)(2)(i)(A), (B) or (D)” and add “sections 2(f)(2)(i)(A), (B), or (D)” in their place;

■ 4. In paragraph (f)(2)(i)(A), remove the words “billing date for the crop year” and add “billing date for the crop year.” in their place;

■ 5. In paragraph (f)(2)(i)(B), remove the words “delinquent debt” and add “delinquent debt.” in their place;

■ 6. Revise paragraph (f)(2)(i)(D);

■ 7. Revise paragraph (f)(4) and (5); and

■ 8. In paragraph (g)(3)(i), remove the words “cancellation date and” and add “cancellation date, and” in their place;

■ g. In section 3:

■ 1. Revise paragraph (c)(5)(ii);

■ 2. Revise paragraph (f)(1)(ii);

■ 3. In paragraph (h)(2)(ii), remove the word “two” and add “2” in its place;

■ 4. In paragraph (h)(3)(ii), remove the word “herein” and add “in section 3(h)(3)(i)” in its place; and

■ 5. In paragraph (i) introductory text, remove the words “applicable to” and add “applicable to” in their place;

■ h. In section 4, revise paragraph (b);

■ i. In section 5:

■ 1. In paragraph (b)(5) introductory text, remove the word “four” and add “4” in its place;

■ 2. In paragraph (b)(5)(i)(A), remove the word “three” and add “3” in its place;

■ 3. In paragraph (b)(5)(i)(B), remove the word “two” and add “2” in its place;

■ 4. In paragraph (b)(5)(i)(C), remove the word “one” and add “1” in its place; and

■ 5. In paragraph (c)(3), remove the word “four” and add “4” in its place;

■ j. In section 6:

■ 1. In paragraph (d)(1), remove the words “without our consent (Consent)” and add “without our consent. (Consent)” in their place and remove the words “by the policy)” and add “by the policy.)” in their place; and

■ 2. In paragraph (h), remove the words “prevented planting payment or replanting payment” and add “prevented planting payment, or replanting payment” in their place;

■ k. In section 7:

■ 1. In paragraph (e)(1), remove the words “in excess of” and add “exceeding” in their place;

■ 2. In paragraph (e)(4)(iii), remove the word “one” and add “1” in its place; and

■ 3. Revise paragraph (g);

■ l. In section 8, in paragraph (b)(2), remove the words “premium rate, etc.)” and add “premium rate, etc.)” in their place;

■ m. In section 9, in paragraph (c) introductory text, remove the word “states” and add “States” in its place;

■ n. In section 10, in paragraph (a)(2)(ii) introductory text, remove the words “power of attorney, etc.)” and add “power of attorney, etc.)” in their place;

■ o. In section 12:

■ 1. In paragraph (a), remove the words “fire, terrorism, etc.)” and add “fire, terrorism, etc.)” in their place; and

■ 2. In paragraph (c), remove the words “designed limits (For” and add “designed limits. (For” in their place;

■ p. In section 14:

■ 1. In paragraph (e)(3)(i), remove the words “in the unit (When” and add “in the unit. (When” in their place; and

■ 2. In paragraph (i), remove the words “the Federal Crop Insurance Corporation” and add “FCIC” in their place;

■ q. In section 15:

■ 1. In paragraphs (h)(5)(ii), (i)(1), and (i)(2) remove the words “two of the last four” wherever they appear and add “2 of the last 4” in their place;

■ 2. In paragraph (i)(3)(i), remove the words “2019 and 50 of those acres were double cropped with soybeans; and 100 acres of wheat planted in 2020” and add “2024 and 50 of those acres were double cropped with soybeans; and 100 acres of wheat planted in 2025” in their place;

■ 3. In paragraph (i)(3)(ii), remove the words “2019 and 70 divided by 100 equals 70 percent of the first insured crop acres that were double cropped in 2020” and add “2024 and 70 divided by 100 equals 70 percent of the first insured crop acres that were double cropped in 2025” in their place;

■ 4. In paragraph (i)(3)(iv), remove the year “2021” and add “2026” in its place; and

■ 5. In paragraph (j), remove the words “in excess of” and add “exceeding” in their place;

■ r. In section 17:

■ 1. In paragraph (d)(1)(ii)(A)(2), remove the words “Service or” and add “Service, or” in their place;

■ 2. In paragraph (e)(1)(i) introductory text, remove the words “one or more of the four” and add “1 or more of the 4” in their place;

■ 3. In paragraph (e)(1)(i)(A), remove the words “one of the four” and add “1 of the 4” in their place;

■ 4. In paragraph (e)(1)(i)(C), remove the words “sections 17(e)(1)(i)(B)(1), (2) and (3)” and add “sections 17(e)(1)(i)(B)(1), (2), and (3)” in their place;

■ 5. In paragraph (e)(1)(ii) introductory text and (e)(1)(iii)(A)(2), remove the word “four” wherever it appears and add “4” in its place;

■ 6. In paragraph (f)(1)(i), remove the words “one of the four” and add “1 of the 4” in their place;

■ 7. In paragraph (f)(4)(ii) introductory text, remove the word “four” and add “4” in its place;

■ 8. In paragraph (f)(8)(i)(E)(1), add the word “and” at the end;

■ 9. Remove paragraph (f)(8)(i)(E)(2);

■ 10. Redesignate paragraph (f)(8)(i)(E)(3) as paragraph (f)(8)(i)(E)(2);

■ 11. Remove paragraph (f)(8)(ii);

■ 12. Redesignate paragraph (f)(8)(iii) as (f)(8)(ii);

■ 13. Revise newly redesignated paragraph (f)(8)(ii); and

■ 14. In paragraph (f)(11) introductory text and (f)(11)(i), remove the words “one of the four” wherever they appear and add “1 of the 4” in their place;

■ s. In section 18:

■ 1. In paragraph (d)(4), remove the words “insurance provider (No” and add “insurance provider. (No” in their place and remove the words “this section)” and add “this section.)” in their place;

■ 2. Revise paragraph (e)(2)(ii);

■ 3. In paragraph (f)(2)(i) introductory text and paragraph (f)(2)(i)(B), remove

the word “three” wherever it appears and add “3” in its place;

■ 4. In paragraph (f)(2)(i)(B)(3), remove the word “ten” and add “10” in its place;

■ 5. In paragraph (f)(2)(ii) introductory text and paragraph (f)(2)(ii)(B), remove the word “three” wherever it appears and add “3” in its place;

■ 6. In paragraph (f)(2)(ii)(B)(3), remove the word “ten” and add “10” in its place;

■ 7. Revise paragraph (f)(2)(ii)(C); and

■ 8. In paragraph (k)(2), remove the text “i.e.” and add “i.e.” in its place;

■ t. In section 20 [For FCIC Policies], in paragraphs (d) and (e)(1), remove the word “one” wherever it appears and add “1” in its place;

■ u. In section 20 [For Reinsured Policies]:

■ 1. Revise paragraph (a)(1)(ii);

■ 2. Revise paragraph (a)(2);

■ 3. In paragraph (b)(2), remove the words “judicial review” and add “a judicial review as described in section 20(i)” in their place;

■ 4. In paragraph (b)(3), remove the words “judicial review is sought, suit must be filed not later than one year” and add “a judicial review as described in section 20(i) is sought, suit must be filed not later than 1 year” in their place;

■ 5. Revise paragraph (c);

■ 6. In paragraphs (d)(2)(ii)(C) and (e)(1), remove the word “one” wherever it appears and add “1” in its place;

■ 7. In paragraph (f), remove the word “state” and add “State” in its place; and

■ 8. In paragraph (i), remove the words “USDA/RMA/Deputy Administrator of Compliance/Stop 0806, 1400 Independence Avenue SW, Washington, DC 20250–0806” and add “USDA/RMA/Deputy Administrator for Compliance/Stop 0806, 1400 Independence Avenue SW, Washington, DC 20250–0806” in their place;

■ v. In section 21:

■ 1. In paragraph (b)(1), remove the word “three” and add “3” in its place;

■ 2. Revise paragraph (b)(2); and

■ 3. In paragraph (c), remove the word “three” and add “3” in its place;

■ w. In section 26, remove the text “(41 U.S.C. 7611)” and add “(41 U.S.C. 7109)” in its place;

■ x. In section 34:

■ 1. In paragraph (a)(1)(iii), remove the word “herein;” and add “in section 34(a).” in its place;

■ 2. Revise paragraphs (a)(2)(i)(A) through (G);

■ 3. In paragraph (a)(2)(ii), remove the words “if sections are the basis for optional units” and add “if optional units are available by sections” in their place;

■ 4. Revise paragraph (a)(3) introductory text; and

■ 5. In paragraph (b)(2), add a period following the words “report for that crop year”;

■ y. In section 36, revise paragraphs (a)(1)(i) and (ii); and

■ z. In section 37, in paragraph (g), remove the words “in excess of” and add “exceeding” in their place.

The revisions and additions read as follows:

§ 457.8 The application and policy.

* * * * *

Common Crop Insurance Policy

* * * * *

1. Definitions

* * * * *

Application. The form required to be completed by you and accepted by us before insurance coverage commences. This form must be completed and filed in your agent’s office not later than the sales closing date of the initial insurance year for each crop for which insurance coverage is requested.

* * * * *

Beginning farmer or rancher. An individual who has not actively operated and managed a farm or ranch in any State, with an insurable interest in a crop or livestock as an owner-operator, landlord, tenant, or sharecropper for more than 10 crop years. An individual’s insurable interest in any crop year may be excluded at the request of the individual if the interest was held by the individual while: (1) under the age of 18; (2) in full-time military service of the United States; or (3) in post-secondary education. A person other than an individual may be eligible for beginning farmer or rancher benefits if there is at least one individual substantial beneficial interest holder and all individual substantial beneficial interest holders qualify as a beginning farmer or rancher.

* * * * *

Cancellation. When the policy is no longer in effect as of the cancellation date.

* * * * *

FAA. The Federal Arbitration Act found at 9 U.S.C. 1 *et seq.*

* * * * *

Termination. When the policy is no longer in effect as of the date specified in the policy.

* * * * *

2. Life of Policy, Cancellation, and Termination

* * * * *

(f) * * *

(2) * * *

(i) * * *

(D) For execution of a written payment agreement and failure to make any scheduled payment, the termination date for the crop year prior to the crop year in which you failed to make the scheduled payment (for this purpose only, the crop year will start the day after the termination date and end on the next termination date, for example, if the termination date is November 30 and you fail to make a payment on November 15, 2025, your policy will terminate on November 30, 2024, for the 2025 crop year).

* * * * *

(4) If cancellation, voidance, or termination of insurance coverage occurs for any reason, including but not limited to indebtedness, suspension, debarment, disqualification, cancellation by you or us, or violation of the controlled substance provisions of the Food Security Act of 1985, a new application must be filed for the crop.

(i) Insurance coverage will not be provided if you are ineligible under the contract or under any Federal statute or regulation.

(ii) After you become eligible for crop insurance, if you want to obtain coverage for your crops, you must submit a new application on or before the sales closing date for the crop (since applications for crop insurance cannot be accepted after the sales closing date, if you make any payment after the sales closing date, you cannot apply for insurance until the next crop year).

(5) For example, for the 2025 crop year, if crop A, with a termination date of October 31, 2024, and crop B, with a termination date of March 15, 2025, are insured and you do not pay the premium for crop A by the termination date, you are ineligible for crop insurance as of October 31, 2024, and crop A’s policy is terminated as of that date. Crop B’s policy does not terminate until March 15, 2025, and an indemnity for the 2024 crop year may still be owed. If you enter into a written payment agreement on September 25, 2025, the earliest date by which you can obtain crop insurance for crop A is to apply for crop insurance by the October 31, 2025, sales closing date and for crop B is to apply for crop insurance by the March 15, 2026, sales closing date. If you fail to make a payment that was scheduled to be made on April 1, 2026, your policy will terminate as of October 31, 2025, for crop A, and March 15, 2026, for crop B, and no indemnity, prevented planting payment, or replanting payment will be due for that crop year for either crop. You will not

be eligible to apply for crop insurance for any crop until after the amounts owed are paid in full or you have your debts discharged in bankruptcy.

* * * * *

3. Insurance Guarantees, Coverage Levels, and Prices

* * * * *

(c) * * *

(5) * * *

(ii) For the harvest price:

(A) Notice will be provided on RMA's website;

(B) The harvest price will equal the projected price; and

(C) Your premium will be recalculated as though you had elected yield protection. Any premium previously paid exceeding the new amount will be returned to you.

* * * * *

(f) * * *

(1) * * *

(ii) If you are an insured who transferred your policy to us for the current crop year, you may, without penalty, report your completed and signed production report for the prior crop year to us on or before the production reporting date instead of providing a completed and signed production report to your previous insurance provider by the insured's production reporting date.

* * * * *

4. Contract Changes

* * * * *

(b) Any changes in policy provisions, amounts of insurance, premium rates, program dates, price elections or the Commodity Exchange Price Provisions, if applicable, can be viewed on RMA's website not later than the contract change date contained in the Crop Provisions except:

(1) As specified in section 3; or

(2) To correct clear errors (for example, the price for oats was announced at \$25.00 per bushel instead of \$2.50 per bushel or the final planting date should be May 10 but the final planting date in the Special Provisions states August 10).

* * * * *

7. Annual Premium and Administrative Fees

* * * * *

(g) Additional premium subsidy—If you qualify as a beginning farmer or rancher, or veteran farmer or rancher, the premium subsidy that you would otherwise receive will be increased, unless otherwise specified in the Special Provisions. If you qualify as:

(1) A beginning farmer or rancher, your premium subsidy will be increased by:

(i) 15 percentage points for the first through second crop years;

(ii) 13 percentage points for the third crop year;

(iii) 11 percentage points for the fourth crop year; and

(iv) 10 percentage points for the fifth through tenth crop years;

(2) A veteran farmer or rancher, your premium subsidy will be increased by 10 percentage points; or

(3) Both a beginning farmer or rancher and a veteran farmer or rancher, your premium subsidy will equal that of the beginning farmer or rancher, which is equivalent or higher.

* * * * *

17. Prevented Planting

* * * * *

(f) * * *

(8) * * *

(ii) Once any acreage does not satisfy the requirements in section 17(f)(8)(i)(E), such acreage will be considered physically unavailable for planting until the acreage has been planted to a crop in accordance with 17(f)(8)(i)(E) for 2 consecutive crop years.

* * * * *

18. Written Agreements

* * * * *

(e) * * *

(2) * * *

(ii) On or before the cancellation date to insure a crop in a county that does not have actuarial documents for the crop (if the Crop Provisions or Special Provisions do not provide a cancellation date for the county, the cancellation date for the requested crop or other insurable crops with similar agronomic conditions that have similar final planting and harvesting dates will be applicable); or

* * * * *

(f) * * *

(2) * * *

(ii) * * *

(C) If you (or anyone with a substantial beneficial interest in you) have at least 1 year of production records, but less than 3 years of production records, for the crop in the county or area but have production records for a similar crop in the county or area such that the combination of both sets of records results in at least 3 years of production records, you must provide the information required in sections 18(f)(2)(i)(A) and (B) for the years you (or anyone with a substantial beneficial interest in you) planted the crop (or produced a crop if the crop is

a perennial crop) in the county or area and the information required in sections 18(f)(2)(ii)(A) and (B) regarding the similar crop for the remaining years; and

* * * * *

[For Reinsured Policies]

20. Mediation, Arbitration, Appeal, Reconsideration, and Administrative and Judicial Review

(a) * * *

(1) * * *

(ii) An arbitrator does not have the authority to:

(A) Interpret the policy or FCIC procedures; or

(B) Disregard or fail to comply with a final agency determination or FCIC interpretation issued in accordance with 7 CFR part 400, subpart X. An arbitration award that is inconsistent with section 20 may be appealed in accordance with the FAA.

* * * * *

(2) Unless the dispute is resolved through mediation, the arbitrator must provide to you and us a written statement describing the issues in dispute, the factual findings, the determinations and the amount and basis for any award and breakdown by claim for any award. The statement must also include any amounts awarded for interest. The arbitrator does not have the authority to issue an award that does not conform to section 20. Failure of the arbitrator to provide such written statement may be appealed in accordance with the FAA. All agreements reached through settlement, including those resulting from mediation, must be in writing and contain at a minimum a statement of the issues in dispute and the amount of the settlement.

* * * * *

(c) The FAA governs arbitrations initiated under section 20(b)(1) and any decision rendered in arbitration is binding on you and us unless vacated, modified, or corrected in accordance with the FAA.

* * * * *

21. Access to Insured Crop and Records, and Record Retention

* * * * *

(b) * * *

(2) All records used to establish the amount of production you certified on your production reports used to compute your approved yield for 3 years after the calendar date for the end of the insurance period for the crop year for which you initially certified such records, unless such records have already been provided to us. (For example, if you are a new insured and

you certify 2017 through 2020 crop year production records in 2021 to determine your approved yield for the 2021 crop year, you must retain all records from the 2017 through 2020 crop years through the 2024 crop year. If you subsequently certify records of the 2021 crop year in 2022 to determine your approved yield for the 2022 crop year, you must retain the 2021 crop year records through the 2025 crop year and so forth for each subsequent year of production records certified.); and

* * * * *

34. Units

- (a) * * *
(2) * * *
(i) * * *

(A) Two or more sections, if optional units are available by sections where the insured acreage is located;

(B) Two or more section equivalents, if optional units are available by section equivalents where the insured acreage is located or are applicable to the insured acreage;

(C) Two or more FSA farm numbers, if optional units are available by FSA farm numbers where the insured acreage is located;

(D) Any combination of two or more sections, section equivalents, or FSA farm numbers, if optional units are available by more than one of these where the acreage is located or are applicable to the insured acreage (for example, if a portion of your acreage is located where optional units are allowed by sections and another portion of your acreage is located where optional units are allowed by FSA farm numbers, you may qualify for an enterprise unit based on a combination of these two parcels);

(E) One section, section equivalent, or FSA farm number that contains at least 660 planted acres of the insured crop. You may qualify under this paragraph based only on the type of parcel that is utilized to establish optional units where your insured acreage is located (for example, if optional units are available by two or more sections where the insured acreage is located, you may qualify for an enterprise unit if you have at least 660 planted acres of the insured crop in one section);

(F) Two or more units established by written agreement; or

(G) Two or more non-contiguous parcels of land, if optional units by non-contiguous parcels of land are allowed by the Crop Provisions or Special Provisions and optional units are available where the insured acreage is located;

* * * * *

(3) Whole-Farm Unit—For a whole-farm unit:

* * * * *

36. Yield Options

* * * * *

(a) * * *

(1) * * *

(i) Each election made in section 36(a)(1) must be made on or before the production reporting date for the insured crop and each such election will remain in effect for succeeding crop years unless canceled by the production reporting date for the succeeding crop year. If you cancel an election, the actual yield will be used in the APH database. For example, if you elected to substitute yields in your APH database for the 2024 and 2025 crop years, for any subsequent crop year, you can elect to cancel the substitution for either or both crop years.

(ii) Each excluded actual yield will be replaced with a yield equal to 60 percent of the applicable transitional yield for the crop year in which the yield is being replaced, unless you qualify as a beginning farmer or rancher, or veteran farmer or rancher, in which case the excluded actual yield will be replaced with a yield equal to 80 percent of the applicable transitional yield for the crop year in which the yield is being replaced. (For example, if you elect to exclude a 2024 crop year actual yield, the transitional yield in effect for the 2024 crop year in the county will be used. If you also elect to exclude a 2025 crop year actual yield, the transitional yield in effect for the 2025 crop year in the county will be used.) The replacement yields will be used in the same manner as actual yields for the purpose of calculating the approved yield.

* * * * *

■ 15. Amend § 457.104 as follows:

■ a. Revise the introductory text and the undesignated text at the beginning of the “Cotton Crop Provisions”;

■ b. In the definitions of “Planted acreage” and “Production guarantee (per acre)”, remove the word “contained”;

■ c. In section 2, revise the section heading;

■ d. Revise section 4;

■ e. In section 6, in the introductory text, remove the words “the provisions of”;

■ f. In section 7, revise paragraph (b);

■ g. In section 8:

■ 1. In the introductory text, remove the words “the provisions of”; and

■ 2. In paragraph (d), remove the word “measures” and add “measures” in its place;

■ h. In section 10:

■ 1. Revise paragraph (b)(6) and the example paragraphs between paragraphs (b)(6) and (c);

■ 2. In paragraph (c)(1)(iii), remove the word “subsection” and add “section” in its place;

■ 3. In paragraph (c)(1)(iv)(A), remove the words “to us (The)” and add “to us. (The)” in their place and remove the words “to count)” and add “to count.” in their place; and

■ 4. Revise paragraph (d); and

■ i. In section 11, in paragraph (a), remove the words “the provisions of.”

The revisions read as follows:

§ 457.104 Cotton crop insurance provisions.

The Cotton Crop Insurance Provisions for the 2026 and succeeding crop years are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Cotton Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Cotton Crop Provisions and corresponding Commodity Exchange Price Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

* * * * *

2. Insurance Guarantees, Coverage Levels, and Prices

* * * * *

4. Cancellation and Termination Dates

In accordance with section 2 of the Basic Provisions, the cancellation and termination dates are specified in the Special Provisions.

* * * * *

7. Insurance Period

* * * * *

(b) In accordance with section 11 of the Basic Provisions, the calendar date for the end of the insurance period is specified in the Special Provisions.

* * * * *

10. Settlement of Claim

* * * * *

(b) * * *

(6) Multiplying the result of section 10(b)(5) by your share.

Example for Section 10(b)

You have 100 percent share in 50 acres of cotton in the unit with a production guarantee (per acre) of 525 pounds, your projected price is \$.75 per pound, your harvest price is \$.80 per

pound, and your production to count is 25,000 pounds.

If you elected yield protection:

(1) $50 \text{ acres} \times (525\text{-pound production guarantee (per acre)} \times \$0.75 \text{ per pound projected price}) = \$19,687.50$ value of the production guarantee;

(2) Not applicable;

(3) $25,000\text{-pound production to count} \times \$0.75 \text{ per pound projected price} = \$18,750.00$ value of the production to count;

(4) Not applicable;

(5) $\$19,687.50 - \$18,750.00 = \$937.50$;

(6) $\$937.50 \times 1.000 \text{ share} = \$938.00$

indemnity; or

If you elected revenue protection:

(1) $50 \text{ acres} \times (525\text{-pound production guarantee (per acre)} \times \$0.80 \text{ per pound harvest price}) = \$21,000.00$ revenue protection guarantee;

(2) Not applicable;

(3) $25,000\text{-pound production to count} \times \$0.80 \text{ per pound harvest price} = \$20,000.00$ value of the production to count;

(4) Not applicable;

(5) $\$21,000.00 - \$20,000.00 = \$1,000.00$;

(6) $\$1,000.00 \times 1.000 \text{ share} = \$1,000.00$ indemnity payment.

End of example.

* * * * *

(d) Mature white cotton may be adjusted for quality when production has been damaged by insured causes. Such production to count will be reduced if Price A is less than 90 percent of Price B.

(1) Price B will be established by adding the current year's Farm Service Agency (FSA) premiums or discounts associated with the predominant cotton quality characteristics contained in the Special Provisions to the current year's FSA Upland Cotton National Average Loan Rate, or as specified in the Special Provisions.

(2) Price A is defined as the loan value per pound for the bale determined in accordance with the FSA Schedule of Premiums and Discounts for the applicable crop year, or as specified in the Special Provisions.

(3) If eligible for adjustment, the amount of production to count will be determined by multiplying the number of pounds of such production by the factor derived from dividing Price A by Price B.

* * * * *

■ 16. Amend § 457.109 as follows:

■ a. In the regulation heading, remove the words "Beet Crop Insurance Provisions" and add "beet crop insurance provisions" in their place;

■ b. Revise the introductory text and the undesignated text at the beginning of the "Sugar Beet Crop Provisions";

■ c. In section 1:

■ 1. Remove the definition of "Crop year";

■ 2. In the definition of "Planted acreage", remove the word "contained"; and

■ 3. In the definition of "Practical to replant", remove the words "in section 1 of the" and add "in the" in their place;

■ d. In section 2, remove the word "section 34" and add "section 34(b)" in its place;

■ e. In section 3:

■ 1. In paragraph (b)(1) introductory text, remove the text "(60%)"; and

■ 2. In paragraph (b)(2), remove the text "(100%)";

■ f. In section 4, remove the words "the provisions of", and remove the word "states" and add "States" in its place;

■ g. In section 5, remove the words "August 31 for California and March 15 for all other states" and add "specified in the Special Provisions" in their place;

■ h. In section 8, in paragraphs (b)(1) and (b)(4), remove the words "of these Crop Provisions" wherever they appear;

■ i. In section 9, in the introductory text, remove the words "the provisions of";

■ j. In section 11, in the introductory text, remove the words "the provisions of";

■ k. In section 12:

■ 1. Revise the section heading; and

■ 2. In paragraph (a), remove the text "(90%)";

■ l. In section 14:

■ 1. In paragraph (b)(1), remove the words "production guarantee" and add "production guarantee (per acre)" in their place;

■ 2. Revise paragraph (c)(1)(iv); and

■ 3. In paragraph (c)(1)(v)(A), remove the words "to us (The" and add "to us. (The" in their place, and remove the words "to count)" and add "to count.)" in their place;

■ m. In section 18, in paragraphs (b)(5)(i), (ii), and (iii), remove the word "unit" wherever it appears and add "applicable APH database" in its place.

The revisions read as follows:

§ 457.109 Sugar beet crop insurance provisions.

The Sugar Beet Crop Insurance Provisions effective for the 2026 and succeeding crop years in States with a November 30 contract change date and for the 2027 and succeeding crop years in all other States, are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Sugar Beet Crop Provisions

In return for your payment of premium and administrative fee for

coverage, these Sugar Beet Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions subject to the terms and conditions in your policy.

* * * * *

12. Replanting Payment

* * * * *

14. Settlement of Claim

* * * * *

(c) * * *

(1) * * *

(iv) Only appraised production exceeding the difference between the first and final stage production guarantee for acreage that does not qualify for the final stage guarantee will be counted, except that all production from acreage subject to section 14(c)(1)(i) and (ii) will be counted; and

* * * * *

■ 17. Amend § 457.125 as follows:

■ a. Revise the undesignated text preceding section 1;

■ b. In section 1:

■ 1. Remove the definition of "Nurse crop (companion crop)"; and

■ 2. In the definition of "Value per pound", remove the words "in excess of" and add "exceeding" in their place;

■ c. Revise sections 2 through 4;

■ d. In section 5, in the introductory text, remove the words "(Insured Crop)";

■ e. In section 6:

■ 1. In the introductory text, remove the words "the provisions of section 9 (Insurable Acreage)" and add "section 9" in their place; and

■ 2. In paragraph (a), remove the words "we agree in writing" and add "by written agreement" in their place;

■ f. In section 7, remove the words "the provisions of section 11 (Insurance Period)" and add "section 11" in their place;

■ g. In section 8, in the introductory text, remove the words "the provisions of section 12 (Causes of Loss)" and add "section 12" in their place;

■ h. In section 9:

■ 1. In paragraph (a), remove the words "(Replanting Payment)"; and

■ 2. Revise paragraph (b);

■ i. In section 10, remove the words "(Duties in the Event of Damage or Loss)"; and

■ j. In section 11:

■ 1. Revise paragraph (b)(7);

■ 2. Add example paragraphs between (b)(7) and (c);

■ 3. In paragraph (c)(1)(iv)(A), remove the words "to us (The" and add "to us. (The" in their place and remove the words "to count)" and add "to count.)" in their place;

- 4. In paragraphs (d)(1) and (2)(ii), remove the words “in excess of” wherever they appear and add “exceeding” in their place;
- 5. Remove paragraph (d)(3)(ii);
- 6. Redesignate paragraphs (d)(3)(iii) through (v) as paragraphs (d)(3)(ii) through (iv);
- 7. In newly redesignated paragraph (d)(3)(iii)(C), remove the words “is in compliance” and add “complies” in their place;
- 8. In paragraph (d)(4) introductory text, remove the words “in sections 11(d) (2) and (3)” and add “in sections 11(d)(2) and (3)” in their place; and
- 9. In paragraph (d)(4)(ii)(A)(3), remove the word “one” and add “1” in its place.

The revisions and additions read as follows:

§ 457.125 Safflower crop insurance provisions.

The Safflower Crop Insurance Provisions for the 2026 and succeeding crop years for counties with a contract change date of November 30, and for the 2027 and succeeding crop years for counties with a contract change date of August 31, are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Safflower Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Safflower Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

* * * * *

2. Insurance Guarantees, Coverage Levels, and Prices

In addition to the requirements of section 3 of the Basic Provisions (§ 457.8), you may select only 1 price election for all the safflower in the county insured under this policy unless the Special Provisions provide different price elections by type, in which case you may select 1 price election for each safflower type designated in the Special Provisions. The price elections you choose for each type must have the same percentage relationship to the maximum price offered by us for each type. For example, if you choose 100 percent of the maximum price election for 1 type, you must also choose 100 percent of the maximum price election for all other types.

3. Contract Changes

In accordance with section 4 of the Basic Provisions (§ 457.8), the contract change date is August 31 preceding the cancellation date for California, and November 30 preceding the cancellation date for all other States.

4. Cancellation and Termination Dates

In accordance with section 2 of the Basic Provisions (§ 457.8), the cancellation and termination dates are specified in the Special Provisions.

* * * * *

9. Replanting Payment

* * * * *

(b) The amount of the replanting payment per acre will be the lesser of the actual cost of replanting or:

- (1) The following values:
 - (i) The percentage of production guarantee (per acre) stated in the actuarial documents multiplied by your production guarantee (per acre); or
 - (ii) The number of pounds (per acre) stated in the actuarial documents;
- (2) Multiplied by your price election; and
- (3) Multiplied by your insured share.

* * * * *

11. Settlement of Claim

* * * * *

- (b) * * *
 - (7) Multiplying the result in section 11(b)(6) by your share.

Example for Section 11(b)

You have a 100 percent share in 400 acres of safflower in the unit, with a 700-pound production guarantee (per acre) and a price election of \$0.25 per pound. Due to insurable causes, you are only able to harvest 200,000 pounds of safflower. Your indemnity would be calculated as follows:

- (1) 400 acres × 700 pounds = 280,000 pounds production guarantee;
- (2) 280,000 pounds × \$0.25 per pound price election = \$70,000 value of the production guarantee;
- (3) \$70,000 value of the production guarantee;
- (4) 200,000 pounds × \$0.25 per pound = \$50,000 value of production to count;
- (5) \$50,000 value of production to count;
- (6) \$70,000 – \$50,000 = \$20,000 loss; and
- (7) \$20,000 × 1.000 share = \$20,000 indemnity payment.

End of example.

* * * * *

■ 18. Amend § 457.128 as follows:

- a. Revise the introductory text and the undesignated text at the beginning of the “Guaranteed Production Plan of Fresh Market Tomato Crop Provisions”;

■ b. In section 1:

- 1. In the definition of “Acre”, remove the words “Forty-three thousand five hundred sixty (43,560)” and add “43,560” in their place and remove the word “six” wherever it appears and add “6” in its place;
- 2. In the definition of “Mature green tomato”, redesignate paragraphs (a) through (d) as paragraphs (1) through (4);
- 3. Revise the definition of “Potential production”; and
- 4. In the definition of “Practical to replant”, remove the words “of “Practical to replant” contained in section 1 of” and add “in” in their place;
- c. In section 2:
 - 1. Revise paragraph (b); and
 - 2. Add paragraph (c);
- d. In section 3:
 - 1. In paragraph (b) introductory text, remove the words “production guarantees per acre” and add “production guarantees (per acre)” in their place;
 - 2. In paragraph (b)(2), remove the word “states” and add “States” in its place;
 - 3. In paragraph (c), remove the words “production guarantee” and add “production guarantee (per acre)” in their place; and
 - 4. In paragraph (d), remove the words “cherry, roma” and add “cherry, grape, roma” in their place;
- e. Revise section 5;
- f. In section 6, in paragraph (a), remove the words “the provisions of”;
- g. In section 7, remove the words “contained in the Basic Provisions (§ 457.8), for” and add “in the Basic Provisions (§ 457.8) for” in their place and remove the words “production guarantee” and add “production guarantee (per acre)” in their place;
- h. In section 8, in paragraph (e)(4), remove the words “Cherry, roma” and add “Cherry, grape, roma” in their place;
- i. In section 9:
 - 1. In paragraph (a) introductory text, remove the words “the provisions of”; and
 - 2. In paragraphs (a)(2)(i)(B) and (b), remove the words “one of the three” wherever they appear and add “1 of the 3” in their place;
- j. In section 10:
 - 1. In the introductory text, remove the words “the provisions of”; and
 - 2. Revise paragraph (b)(7);
- k. In section 11, in paragraph (a) introductory text, remove the words “the provisions of”;
- l. In section 12:
 - 1. In paragraph (a), remove the words “in excess of” and add “exceeding” in their place;

- 2. Revise paragraph (b); and
 - 3. In paragraph (c), remove the words “contained in section 13” and add “in section 13” in their place;
 - m. In section 13:
 - 1. In paragraphs (b)(1) and (c)(1)(i) introductory text, remove the words “production guarantee” wherever they appear and add “production guarantee (per acre)” in their place;
 - 2. Revise paragraph (c)(1)(iii)(A);
 - 3. In paragraph (c)(1)(iii)(B), remove the words “cherry, roma” and add “cherry, grape, roma,” in their place;
 - 4. In paragraph (c)(1)(v)(A), remove the words “to us (The” and add “to us. (The” in their place and remove the words “to count)” and add “to count.)” in their place;
 - 5. Revise paragraph (c)(2)(ii)(A); and
 - 6. In paragraph (c)(2)(ii)(B), remove the words “cherry, roma” and add “cherry, grape, roma” in their place.
- The revisions read as follows:

§ 457.128 Guaranteed production plan of fresh market tomato crop insurance provisions.

The Guaranteed Production Plan of Fresh Market Tomato Crop Insurance Provisions for the 2026 and succeeding crop years for all counties with a contract change date of December 31, and for the 2027 and succeeding crop years for all counties with a contract change date of September 30, are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Guaranteed Production Plan of Fresh Market Tomato Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Guaranteed Production Plan of Fresh Market Tomato Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

1. Definitions

* * * * *

Potential production. The number of cartons per acre of mature green or ripe tomatoes that the tomato plants would have produced by the end of the insurance period:

(1) With a classification size of 6 x 7 (2⁹/₃₂ inch minimum diameter) or larger for all types except cherry, grape, roma, or plum; or

(2) Meeting the criteria specified in the Special Provisions for cherry, grape, roma, or plum types.

* * * * *

2. Unit Division

* * * * *

(b) Optional units may be established by:

(1) Land location as provided in section 34(c)(1) of the Basic Provisions;

(2) Organic or non-organic farming practices as provided in section 34(c)(3) of the Basic Provisions; or

(3) Combination of land location and organic farming practices as provided in section 34(c)(4) of the Basic Provisions.

(c) Optional units by irrigation practice as provided in 34(c)(2) of the Basic Provisions are not applicable.

* * * * *

5. Cancellation and Termination Dates

In accordance with section 2 of the Basic Provisions (§ 457.8), the cancellation and termination dates are specified in the Special Provisions.

* * * * *

10. Insurance Period

* * * * *

(b) * * *

(7) The date shown in the Special Provisions.

* * * * *

12. Replanting Payment

* * * * *

(b) The maximum amount of the replanting payment per acre will be the lesser of:

(1) Your actual cost of replanting; or
(2) The number of cartons (per acre) stated in the actuarial documents multiplied by your:

(i) Price election; and
(ii) Insured share.

* * * * *

13. Settlement of Claim

* * * * *

(c) * * *

(1) * * *

(iii) * * *

(A) With a classification size of 6 x 7 (2⁸/₃₂ inch minimum diameter) or larger and that would grade 85 percent or better U.S. No. 1 for types other than cherry, grape, roma, or plum; or

* * * * *

(2) * * *

(ii) * * *

(A) That grades 85 percent or better U.S. No. 1 with a classification size of 6 x 7 (2⁸/₃₂ inch minimum diameter) or larger for all types except cherry, grape, roma, or plum; or

* * * * *

■ 19. Amend § 457.137 as follows:

■ a. Revise the introductory text and the undesignated text at the beginning of the “Green Pea Crop Provisions”;

■ b. In section 1:

■ 1. In the definition of “Good farming practices”, remove the words “of “good farming practices”;

■ 2. In the definition of “Pod type”, remove the text “e.g.” and add “for example” in its place;

■ 3. In the definition of “Practical to replant”, remove the words “of “practical to replant” in the” and add “in the” in their place;

■ 4. In the definition of “Price election”, remove the words “of “price election””; and

■ 5. Revise the definitions of “Processor contract” and “Production guarantee (per acre)”;

■ c. In section 2:

■ 1. In paragraph (a)(1)(ii), remove the words “in excess of” and add “exceeding” in their place;

■ 2. In paragraph (a)(2)(i), remove the word “Section” and add “section” in its place;

■ 3. Add paragraph (a)(3); and

■ 4. In paragraph (b), remove the word “Section” and add “section” in its place;

■ d. Revise section 5;

■ e. In section 10, in paragraph (a)(4), remove the words “not covered)” and add “not covered.)” in their place;

■ f. In section 12:

■ 1. Revise paragraph (b)(7) and the example paragraphs between paragraphs (b)(7) and (c); and

■ 2. In paragraph (c)(1)(iv)(A), remove the words “to us (The” and add “to us. (The” in their place and remove the words “to count)” and add “to count.)” in their place.

The revisions and additions read as follows:

§ 457.137 Green pea crop insurance provisions.

The Green Pea Crop Insurance Provisions for the 2026 and succeeding crop years are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Green Pea Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Green Pea Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

1. Definitions

* * * * *

Processor contract.

(1) A written contract between the producer and a processor, containing at a minimum:

(i) The producer's commitment to plant and grow green peas, and to deliver the green pea production to the processor;

(ii) The processor's commitment to purchase all the production stated in the processor contract; and

(iii) A base contract price.

(2) Multiple contracts with the same processor that specify amounts of production will be considered as a single processor contract unless the contracts are for different types of green peas.

Production guarantee (per acre). In accordance with the definition in the Basic Provisions, the production guarantee (per acre) is specified in pounds. For shell type peas, the weight will be determined after shelling.

* * * *

2. Unit Division

(a) * * *

(3) Optional units by land location as provided in section 34(c)(1) of the Basic Provisions and irrigation practice as provided in section 34(c)(2) of the Basic Provisions are not applicable.

* * * *

5. Cancellation and Termination Dates

In accordance with section 2 of the Basic Provisions, the cancellation and termination dates are specified in the Special Provisions.

* * * *

12. Settlement of Claim

* * * *

(b) * * *

(7) Multiplying the result of section 12(b)(6) by your share.

Example for Section 12(b)

You have a 100 percent share in 100 acres of shell type green peas in the unit, with a 4,000-pound production guarantee (per acre) and a price election of \$0.15 per pound. You are only able to harvest 200,000 pounds. Your indemnity would be calculated as follows:

(1) 100 acres $\times$ 4,000 pound production guarantee (per acre) = 400,000 pound production guarantee;

(2) 400,000 pounds $\times$ \$0.15 per pound price election = \$60,000.00 value of the production guarantee;

(3) Not applicable;

(4) 200,000 pounds $\times$ \$0.15 per pound price election = \$30,000.00 value of production to count;

(5) Not applicable;

(6) \$60,000.00 – \$30,000.00 =

\$30,000.00 loss; and

(7) \$30,000.00 $\times$ 1.000 share =

\$30,000.00 indemnity payment.

You also have a 100 percent share in 100 acres of pod type green peas in the

same unit, with a 5,000-pound production guarantee (per acre) and a price election of \$0.15 per pound. You are only able to harvest 450,000 pounds. Your total indemnity for both shell type and pod type green peas would be calculated as follows:

(1) 100 acres $\times$ 4,000 pound production guarantee (per acre) = 400,000 pound production guarantee for the shell type, and 100 acres $\times$ 5,000 pound production guarantee (per acre) = 500,000 pound production guarantee for the pod type;

(2) 400,000 pound production guarantee $\times$ \$0.15 per pound price election = \$60,000.00 value of the production guarantee for the shell type, and 500,000 pound production guarantee $\times$ \$0.15 per pound price election = \$75,000.00 value of the production guarantee for the pod type;

(3) \$60,000.00 + \$75,000.00 = \$135,000.00 total value of the production guarantee;

(4) 200,000 pounds $\times$ \$0.15 per pound price election = \$30,000.00 value of production to count for the shell type; and 450,000 pounds $\times$ \$0.15 per pound = \$67,500.00 value of production to count for the pod type;

(5) \$30,000.00 + \$67,500.00 = \$97,500.00 total value of production to count;

(6) \$135,000.00 – \$97,500.00 = \$37,500.00 loss; and

(7) \$37,500.00 loss $\times$ 1.000 share = \$37,500.00 indemnity payment.

End of example.

* * * *

■ 20. Amend § 457.139 as follows:

■ a. Revise the undesignated text preceding section 1;

■ b. In section 1:

■ 1. In the definition of “acre”, remove the words “six feet” wherever they appear and add the words “6 feet” in their place;

■ 2. In the definition of “crop year” remove the word “contained”; and

■ 3. In the definition of “direct marketing”, remove the words “contained in section 1 of” and add “in” in their place;

■ c. In section 2:

■ 1. Revise paragraph (b); and

■ 2. Add paragraph (c);

■ d. In section 3, in paragraph (c), remove the word “contained”;

■ e. In section 5, remove the words “July 31” and add “specified in the Special Provisions” in their place;

■ f. In section 7, remove the words “contained in section 7” and add “in section 7” in their place and remove the text “e.g.” and add “for example” in its place;

■ g. In section 8:

■ 1. In paragraph (b)(5) introductory text, remove the words “one of the three” and add “1 of the 3” in their place; and

■ 2. In paragraph (c)(3), remove the words “direct marketing” and add “direct marketing, unless otherwise provided by Special Provisions” in their place;

■ h. In section 9, in paragraph (a), remove the words “section 9 of the Basic Provisions, that” and add “the provisions of section 9 of the Basic Provisions that” in their place and remove the words “one of the three” and add “1 of the 3” in their place;

■ i. In section 12:

■ 1. Revise the section heading; and

■ 2. Revise paragraphs (a) and (b);

■ j. In section 13, in the introductory text, remove the word “contained”;

■ k. In section 14, in paragraph (c)(2)(iv)(A), remove the words “be used)” and add “be used.)” in their place;

■ l. In section 16, revise paragraph (b) introductory text.

The revisions and additions read as follows:

§ 457.139 Fresh market tomato (dollar plan) crop insurance provisions.

The Fresh Market Tomato (Dollar Plan) Crop Insurance Provisions for the 2027 and succeeding crop years are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Fresh Market Tomato (Dollar Plan) Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Fresh Market Tomato (Dollar Plan) Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions), subject to the terms and conditions in your policy.

* * * *

2. Unit Division

* * * *

(b) Optional units may be established by:

(1) Land location as provided in section 34(c)(1) of the Basic Provisions;

(2) Organic or non-organic farming practices as provided in section 34(c)(3) of the Basic Provisions; or

(3) Combination of land location and organic farming practices as provided in section 34(c)(4) of the Basic Provisions.

(c) Optional units by irrigation practice as provided in 34(c)(2) of the Basic Provisions are not applicable.

* * * *

12. Replanting Payment

(a) In accordance with section 13 of the Basic Provisions, a replanting payment is allowed if the crop is damaged by an insurable cause of loss to the extent that more than 50 percent of the plant stand will not produce tomatoes and it is practical to replant.

(b) The maximum amount of the replanting payment per acre will be the lesser of:

- (1) Your actual cost of replanting; or
- (2) The dollar amount (per acre) stated in the actuarial documents multiplied by your insured share.

* * * * *

16. Minimum Value Option

* * * * *

(b) In lieu of sections 14(c)(3) and (4), the total value of harvested production will be determined as follows:

* * * * *

■ 21. Amend § 457.148 as follows:

■ a. Revise the introductory text and the undesignated text at the beginning of the “Fresh Market Pepper Crop Provisions”;

■ b. In section 1:

■ 1. Revise the definition of “Crop year”;

■ 2. In the definition of “Harvest”, remove the words “of peppers” and add “of mature bell peppers” in their place;

■ 3. In the definition of “Planted acreage”, remove the words “contained in ;section 1 of the Basic Provisions” and add “in the Basic Provisions” in their place;

■ 4. In the definition of “Planting period”, remove the words “fall, winter or spring-planted peppers” and add “spring, summer, fall, or winter planted peppers” in their place;

■ 5. Revise the definition of “Practical to replant”;

■ c. In section 2:

■ 1. Revise paragraph (b);

■ 2. Add paragraph (c);

■ d. In section 3:

■ 1. In paragraph (a), remove the words “(Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities)”;

■ 2. In paragraph (c), remove the words “contained in section 3 (Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities)” and add “in section 3” in their place;

■ e. Revise sections 4 and 5;

■ f. In section 6, in the introductory text, remove the words “(Report of Acreage)”;

■ g. In section 7, remove the words “contained in section 7 (Annual Premium and Administrative Fees)” and add “in section 7” in their place;

■ h. In section 8:

■ 1. In the introductory text, remove the words “(Insured Crop)”;

■ 2. In paragraph (c) introductory text, add a colon at the end;

■ 3. In paragraph (c)(4), remove the words “direct marketing” and add “direct marketing, unless otherwise allowed by the Special Provisions” in their place;

■ i. In section 9:

■ 1. In paragraph (a), remove the words “(Insurable Acreage)”;

■ 2. In paragraph (b) introductory text, remove the words “the provisions of section 9 (Insurable Acreage)” and add “section 9” in their place;

■ j. In section 10:

■ 1. In the introductory text, remove the words “the provisions of section 11 (Insurance Period)” and add “section 11” in their place;

■ 2. Revise paragraph (f);

■ k. In section 11:

■ 1. In paragraph (a) introductory text, remove the words “the provisions of section 12 (Causes of Loss)” and add “section 12” in their place;

■ 2. In paragraph (b) introductory text, remove the words “(Causes of Loss)”;

■ l. In section 12:

■ 1. Revise the section heading;

■ 2. In paragraph (a), remove the words “(Replanting Payment)”;

■ 3. Revise paragraph (b);

■ 4. In paragraph (c), remove the words “contained in section 13 (Replanting Payments)” and add “in section 13” in their place;

■ m. In section 13, in the introductory text, remove the words “contained in section 14 (Duties in the Event of Damage or Loss)” and add “section 14” in their place;

■ n. In section 14:

■ 1. Revise paragraph (b)(4)(ii); and

■ 2. In paragraph (c)(2)(iv)(A), remove the words “actual production (If” and add “actual production. (If” in their place and remove the words “be used)” and add “be used.)” in their place;

■ o. In section 16, in paragraph (b) introductory text, remove the words “the provisions contained in”.

The revisions and additions read as follows:

§ 457.148 Fresh market pepper crop insurance provisions.

The Fresh Market Pepper Crop Insurance Provisions for the 2026 and succeeding crop years for all counties with a contract change date of November 30, and for the 2027 and succeeding crop years for all counties with a contract change date of April 30, are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Fresh Market Pepper Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Fresh Market Pepper Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

1. Definitions

* * * * *

Crop year. In lieu of the definition in the Basic Provisions, a period of time that begins on the first day of the earliest planting period and continues through the end of insurance period for the latest planting period shown in the Special Provisions in your county. The crop year is designated by the calendar year in which fresh market peppers grown during the latest planting period would normally be harvested.

* * * * *

Practical to replant. In addition to the definition in the Basic Provisions (§ 457.8), we may consider marketing windows when determining if it is practical to replant.

* * * * *

2. Unit Division

* * * * *

(b) Optional units may be established by:

(1) Land location as provided in section 34(c)(1) of the Basic Provisions;

(2) Organic or non-organic farming practices as provided in section 34(c)(3) of the Basic Provisions; or

(3) Combination of land location and organic farming practices as provided in section 34(c)(4) of the Basic Provisions.

(c) Optional units by irrigation practice as provided in 34(c)(2) of the Basic Provisions are not applicable.

* * * * *

4. Contract Changes

In accordance with section 4 of the Basic Provisions (§ 457.8), the contract change date is April 30 preceding the July 31 cancellation date and November 30 preceding the March 15 cancellation date.

5. Cancellation and Termination Dates

In accordance with section 2 of the Basic Provisions (§ 457.8), the cancellation and termination dates are specified in the Special Provisions.

* * * * *

10. Insurance Period

* * * * *

(f) Unless otherwise provided in the Special Provisions, the calendar date for the end of the insurance period is:

(1) 165 days after the date of direct-seeding or replanting with seed; or

(2) 150 days after the date of transplanting or replanting with transplants.

* * * * *

12. Replanting Payment

* * * * *

(b) The maximum amount of the replanting payment per acre will be the lesser of:

(1) Your actual cost of replanting; or
(2) The dollar amount (per acre) stated in the actuarial documents multiplied by your insured share.

* * * * *

14. Settlement of Claim

* * * * *

(b) * * *

(4) * * *

(ii) For catastrophic risk protection coverage, the result of multiplying the total value of production to be counted (see section 14(c)) by the percentage contained in the actuarial documents; and

* * * * *

■ 22. Amend § 457.151 as follows:

■ a. Revise the introductory text and the undesignated text at the beginning of the “Forage Seeding Crop Provisions”;

■ b. In section 1:

■ 1. In the definition of “Adequate stand”, redesignate paragraphs (a) and (b) as (1) and (2);

■ 2. In the definition of “Crop year”, remove the words “The period” and add “In lieu of the definition in the Basic Provisions, the period” in their place; and

■ 3. In the definition of “Sales closing date”, remove the words “contained in the Basic” and add “in the Basic” in their place;

■ c. In section 3:

■ 1. Remove the period at the end of the section heading; and

■ 2. Remove the word “contained” in paragraph (c);

■ d. Revise section 5;

■ e. In section 6:

■ 1. Remove the period at the end of the section heading; and

■ 2. Remove the words “of the provisions”;

■ f. In section 8:

■ 1. Remove the period at the end of the section heading; and

■ 2. Remove the words “the provisions of”;

■ g. In section 9(c), remove the words “Special Provisions (You” and add

“Special Provisions. (You” in their place and remove the words “harvest date)” and add “harvest date.)” in their place;

■ h. In section 10, in the introductory text, remove the words “the provisions of”;

■ i. In section 11;

■ 1. In the introductory text, remove the words “the provisions contained in”;

and

■ 2. In paragraph (a)(4) introductory text, remove the word “states” and add “States” in its place;

■ j. In section 12, remove the period at the end of the section heading;

■ k. In section 13:

■ 1. Remove the period at the end of the section heading; and

■ 2. Revise paragraph (b) and the example between paragraph (b) and section 14.

The revisions read as follows:

§ 457.151 Forage seeding crop insurance provisions.

The Forage Seeding Crop Insurance Provisions for the 2026 and succeeding crop years for all counties with a contract change date of November 30, and for the 2027 and succeeding crop years for all counties with a contract change date of April 30, are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Forage Seeding Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Forage Seeding Crop Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

* * * * *

5. Cancellation and Termination Dates

In accordance with section 2 of the Basic Provisions, the cancellation and termination dates are specified in the Special Provisions.

* * * * *

13. Settlement of Claim

* * * * *

(b) Totaling the results in section 13(a).

Example for Section 13

Assume you have a 100 percent share in 30 acres of type A forage in the unit, with an amount of insurance of \$100 per acre. At the time of loss, the following findings are established: 10 acres had a remaining stand of 75 percent of an adequate stand or greater. 20 acres had a remaining stand less than 75 percent

but more than 55 percent of an adequate stand.

You also have a 100 percent share in 20 acres of type B forage in the unit, with an amount of insurance of \$90 per acre. 10 acres had a remaining stand of 75 percent of an adequate stand or greater. 10 acres had a remaining stand less than 55 percent of an adequate stand.

Your indemnity would be calculated as follows:

1. 30 acres × \$100 per acre = \$3,000 amount of insurance for type A; 20 acres × \$90 per acre = \$1,800 amount of insurance for type B;

2. 10 acres with 75% of an adequate stand or greater × \$100 per acre = \$1,000 for type A; 10 acres with 75% of an adequate stand or greater × \$90 per acre = \$900 for type B;

3. 20 acres with less than 75% but greater than 55% of an adequate stand × \$100 per acre × 50 percent = \$1,000 for type A; 0 acres with less than 75% but greater than 55% of an adequate stand × \$90 per acre × 50 percent = \$0 for type B;

4. \$1,000 + \$1,000 = \$2,000 reduction for type A; \$900 + \$0 = \$900 reduction for type B;

5. \$3,000 – \$2,000 = \$1,000 for type A; \$1,800 – \$900 = \$900 for type B

6. \$1,000 × 1.000 share = \$1,000 for type A; \$900 × 1.000 share = \$900 for type B; and

7. \$1,000 + \$900 = \$1,900 total indemnity.

End of example.

* * * * *

■ 23. Amend § 457.161 as follows:

■ a. Revise the introductory text and the undesignated text at the beginning of the “Canola and Rapeseed Crop Provisions”;

■ b. In section 1:

■ 1. In the definition of “Canola”, remove the words “in accordance with” and add “by” in their place;

■ 2. In the definition of “Latest final planting date”, redesignate paragraphs (a) through (c) as paragraphs (1) through (3);

■ 3. In the definitions of “Planted acreage” and “Prevented planting”, remove the word “contained” wherever it appears; and

■ 4. In the definition of “Price of damaged production”, remove the words “of these crop provisions”;

■ c. Revise section 5;

■ d. Revise sections 10(a) and (b);

■ e. In section 12:

■ 1. In the Example for section 12(b) between paragraphs (b)(6) and (c), remove the words “1,350 pound production guarantee” wherever it appears and add “1,350-pound

production guarantee (per acre)” in its place, remove the text “\$17,550.00 – \$13,260.00” and add “\$17,550.00 – \$13,260.00” in its place, and remove the text

“\$17,550.00 – \$12,240.00” and add “\$17,550.00 – \$12,240.00” in its place; ■ 2. In paragraph (c)(1)(iv)(A), remove the words “to us (The” and add “to us. (The” in their place and remove the words “to count)” and add “to count.)” in their place;

■ 3. In paragraph (d)(1), remove the words “in excess of” and add “exceeding” in their place; and

■ 4. In paragraph (d)(3)(iv)(C), remove the words “is in compliance” and add “complies” in their place.

The revision reads as follows:

§ 457.161 Canola and rapeseed crop insurance provisions.

The Canola and Rapeseed Crop Insurance Provisions for the 2026 and succeeding crop years for counties with a contract change date of November 30, and for the 2027 and succeeding crop years for counties with a contract change date of June 30, are as follows:

United States Department of Agriculture

Federal Crop Insurance Corporation

Canola and Rapeseed Crop Provisions

In return for your payment of premium and administrative fee for coverage, these Canola and Rapeseed Crop Provisions and corresponding Commodity Exchange Price Provisions will be attached to and made part of the Common Crop Insurance Policy, Basic Provisions (Basic Provisions) subject to the terms and conditions in your policy.

* * * * *

5. Cancellation and Termination Dates

In accordance with section 2 of the Basic Provisions, the cancellation and termination dates are specified in the Special Provisions.

* * * * *

10. Replanting Payment

(a) A replanting payment is allowed as follows:

(1) You must comply with all requirements regarding replanting payments in section 13 of the Basic Provisions;

(2) The insured crop must be damaged by an insurable cause of loss to the extent that the remaining stand will not produce at least 90 percent of the production guarantee for the acreage; and

(3) The replanted crop must be seeded at a rate sufficient to achieve a total (undamaged and new seeding) plant

population that is considered appropriate by agricultural experts for the insured crop, type, and practice.

(b) Your actual cost will not be used to determine your replanting payment. The amount of the replanting payment per acre will be:

(1) The lesser of the following values:

(i) The percentage of production guarantee (per acre) stated in the actuarial documents multiplied by your production guarantee (per acre); or

(ii) The number of pounds (per acre) stated in the actuarial documents;

(2) Multiplied by your projected price; and

(3) Multiplied by your share.

* * * * *

Richard Fordyce,

Under Secretary, Farm Production and Conservation.

[FR Doc. 2025–21482 Filed 11–26–25; 8:45 am]

BILLING CODE 3410–08–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 328

RIN 3064–AF26

FDIC Official Signs and Advertising Requirements, False Advertising, Misrepresentation of Insured Status, and Misuse of the FDIC’s Name or Logo

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule; delay of compliance date.

SUMMARY: On December 20, 2023, the FDIC adopted a final rule that, among other things, amended the FDIC’s official sign and advertisement of membership requirements for insured depository institutions (IDIs). The current compliance date for requirements related to displaying the official digital sign on IDIs’ digital deposit-taking channels and automated teller machines (ATMs) and like devices is March 1, 2026. The FDIC is delaying the March 1, 2026, compliance date to January 1, 2027. This delay will provide certainty and minimize undue burden on IDIs while the FDIC completes consideration of a proposal to amend requirements related to digital deposit-taking channels and ATMs and like devices.

DATES: The compliance date for the requirements in 12 CFR 328.4 and 328.5, which was initially delayed at 89 FR 84261 (October 22, 2024) and was subsequently delayed at 90 FR 11659

(March 11, 2025), is further delayed to January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

Division of Depositor and Consumer Protection: Monika Jansen, Senior Policy Analyst, 202–898–6781, MoJansen@fdic.gov. Legal Division: Shane Bogusz, Senior Attorney, 202–898–6571, SBogusz@FDIC.gov.

SUPPLEMENTARY INFORMATION: On December 20, 2023, the FDIC adopted a final rule¹ revising the official sign and advertising regulations implementing section 18(a) of the Federal Deposit Insurance Act.²

The final rule became effective on April 1, 2024, and required full compliance with the rule by January 1, 2025. Based upon feedback from IDIs and other industry participants, the FDIC delayed the compliance date for the amendments in subpart A of 12 CFR part 328 to May 1, 2025.³ The delay was intended to provide additional time for IDIs to put in place processes and systems and make technological updates. In March 2025, the compliance date was further delayed as to the requirements in 12 CFR 328.4 and 328.5.⁴ This second delay recognized that the requirements of 12 CFR 328.4 and 328.5, relating to signage requirements for digital deposit-taking channels and ATMs and like devices, continued to generate questions regarding implementation and had the potential to cause consumer confusion. The delay allowed the FDIC to consider proposing changes to these requirements, which it did on August 21, 2025.⁵

Specifically, on August 21, 2025, the FDIC issued a notice of proposed rulemaking seeking comment on a proposal that would amend the requirements of 12 CFR 328.4 and 328.5 to minimize identified implementation issues, reduce burden, and address potential consumer confusion. Given that the FDIC is considering changes to 12 CFR 328.4 and 328.5, the approaching March 1, 2026, compliance deadline for the present requirements of 12 CFR 328.4 and 328.5 has created uncertainty and could impose unnecessary burden on IDIs. To address these concerns, the FDIC is delaying the compliance date for the requirements in 12 CFR 328.4 and 328.5 from March 1, 2026, to January 1, 2027.⁶ This delayed

¹ 89 FR 3504.

² 12 U.S.C. 1828(a).

³ 89 FR 84261 (Oct. 22, 2024).

⁴ 90 FR 11659 (Mar. 11, 2025).

⁵ 90 FR 40767.

⁶ The policies and procedures required by 12 CFR 328.8 for which the compliance date is May 1, 2025, will not need to address the requirements in 12 CFR

compliance date is subject to any changes to these provisions made by any future rulemaking.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on November 25, 2025.

Jennifer M. Jones,

Deputy Executive Secretary.

[FR Doc. 2025–21461 Filed 11–26–25; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–1729; Project Identifier MCAI–2024–00568–T; Amendment 39–23183; AD 2025–22–05]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–12–10, which applied to certain Dassault Aviation Model FALCON 7X airplanes. AD 2022–12–10 required revising the existing airplane flight manual (AFM) to provide emergency procedures for inconsistent or unreliable flight data, emergency and abnormal operations procedures for the generic input/output (GEN I/O) internal module failure, and emergency procedures for additional information. AD 2022–12–10 also required revising the existing minimum equipment list (MEL) for the multi-function probe heating, air data, and inertial reference systems. Since the FAA issued AD 2022–12–10, the manufacturer developed modifications that fix a weak point in the avionics architecture. This AD continues to require the actions in AD 2022–12–10 and removes certain airplanes from the applicability. This AD also requires modification of the avionics system and related revisions to the existing AFM and MEL. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2026.

328.4 or 328.5, until January 1, 2027, the full compliance date for these provisions.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2025–1729; 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, the mandatory continuing airworthiness information (MCAI), 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.

Material Incorporated by Reference:

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

- 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–2025–1729.

FOR FURTHER INFORMATION CONTACT: William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7301; email: *9-AVS-AIR-BACO-COS@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2022–12–10, Amendment 39–22082 (87 FR 45246, July 28, 2022) (AD 2022–12–10). AD 2022–12–10 applied to all Dassault Aviation Model FALCON 7X airplanes, except airplanes having Dassault modification M2091 embodied in production. AD 2022–12–10 required revising the existing AFM to provide emergency procedures for inconsistent or unreliable flight data, emergency and abnormal operations procedures for the GEN I/O internal module failure, and emergency procedures for additional information. AD 2022–12–10 also required revising the operator's existing FAA-approved MEL items for the multi-function probe heating, air data, and inertial reference systems. The FAA issued AD 2022–12–10 to address misleading data on display units, which could reduce safety margins and lead to increased pilot workload, possibly resulting in reduced controllability of the airplane.

The NPRM was published in the **Federal Register** on August 6, 2025 (90 FR 37810). The NPRM was prompted by AD 2023–0003R1, dated September 26, 2024 (EASA AD 2023–0003R1) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that EASA superseded EASA AD 2021–0197, dated August 23, 2021 (which corresponds to AD 2022–12–10), with EASA AD 2022–0145, dated July 12, 2022 (EASA AD 2022–0145). EASA AD 2022–0145 was issued to retain the requirements of EASA AD 2021–0197, exclude airplanes on which Dassault modification M2091 was embodied in production, and require airplane serial numbers (S/Ns) 402 and subsequent with the “EASy III—2nd CERT” or “EASy III—3rd CERT” standard to upgrade the avionics architecture to the “EASy III—4th CERT” standard (modification M2091).

EASA AD 2022–0145, in turn, was superseded by EASA AD 2023–0003, dated January 6, 2023 (EASA AD 2023–0003). EASA AD 2023–0003 was issued to retain the requirements of EASA AD 2022–0145, exclude airplanes on which Dassault modification M2096 or M2097 was embodied in production, and require airplane S/Ns 2 through 400 inclusive to upgrade the avionics architecture to the “EASy II—5th CERT” standard (modification M2096 or M2097, as applicable).

Since EASA AD 2023–0003 was issued, Dassault developed modifications M2055 (for airplane S/Ns 2 through 400 inclusive) and M2059 (for airplane S/Ns 402 and subsequent) that upgrade the avionics architecture to the “EASy IV” standard and issued Dassault Service Bulletin 7X–600, dated November 7, 2022; Dassault Service Bulletin 7X–601, April 24, 2023; and Dassault Service Bulletin 7X–602, June 3, 2023; as applicable, to provide in-service modification instructions. EASA AD 2023–0003 was subsequently revised by EASA AD 2023–0003R1 to exclude airplanes on which modifications M2055 or M2059 were embodied in production and allow incorporation of those modifications in service as an optional method of compliance for modifications M2091, M2096, or M2097, as applicable.

In the NPRM, the FAA proposed to continue to require the actions in AD 2022–12–10 and remove from the applicability airplanes on which Dassault modification M2055, M2059, M2096, or M2097 were embodied in production. The FAA also proposed to require modification of the avionics system and related revisions to the existing AFM and MEL, as specified in

EASA AD 2023–0003R1. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–1729.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. 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, this AD is adopted as proposed in the NPRM.

None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2023–0003R1, which specifies revising the (1) existing AFM to provide emergency procedures for inconsistent or unreliable flight data and emergency and abnormal operations procedures for the GEN I/O internal module failure; (2) existing FAA-approved MEL items for the multi-function probe heating, air data, and inertial reference systems and modular avionic unit (MAU) #1B; and (3) operational suitability manual—flight crew (OSM–FC). This material also specifies procedures for modifying the avionics system and incorporating related AFM and MEL revisions.

This material also describes optional procedures for modifying the avionics architecture to the “EASy IV” standard, revising the existing AFM to incorporate revision 6 or revision 25, as applicable, and revising the existing FAA-approved MEL to incorporate revision 16. Accomplishing the optional modification and AFM revision is an acceptable method of compliance for the applicable modification that upgrades the avionics architecture to “EASy III—4th CERT” or “EASy II—5th CERT” and

related AFM revision. In addition, accomplishing the optional MEL revision is an acceptable method of compliance for the corresponding revisions to MEL items for the multi-function probe heating, air data, and inertial reference systems and MAU #1B.

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.

Interim Action

The preamble to AD 2022–12–10 specifies that the FAA considers that AD “interim action” and that the FAA might consider further rulemaking if a final action is identified. The manufacturer has since developed modifications (*i.e.*, software upgrades) that fix a weak point in the avionics architecture to address the unsafe condition. The FAA has determined that the modifications and related AFM and MEL revisions should be required.

Costs of Compliance

The FAA estimates that this AD affects 160 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2022–12–10 (MEL and AFM revisions).	2 work-hours × \$85 per hour = \$170	\$0	\$170	\$27,200
New actions (modification and AFM and MEL revisions).	10 work-hours × \$85 per hour = \$850	* 0	850	136,000

* The FAA has received no definitive data on which to base the cost estimates for the parts specified in this AD.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
Up to 302 work-hours × \$85 per hour = \$25,670	Up to \$782,394	\$808,064

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

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:

- a. Removing Airworthiness Directive (AD) 2022–12–10, Amendment 39–22082 (87 FR 45246, July 28, 2022); and
- b. Adding the following new AD:

2025–22–05 Dassault Aviation:

Amendment 39–23183; Docket No. FAA–2025–1729; Project Identifier MCAI–2024–00568–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 2, 2026.

(b) Affected ADs

This AD replaces AD 2022–12–10, Amendment 39–22082 (87 FR 45246, July 28, 2022) (AD 2022–12–10).

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 7X airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2023–0003R1, dated September 26, 2024 (EASA AD 2023–0003R1).

Note 1 to paragraph (c): Model FALCON 7X airplanes with Dassault modification M1000 incorporated are commonly referred to as “Model FALCON 8X” as a marketing designation.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by a report of a weak point identified in the Falcon 7X “EASy” avionics architecture, which, coupled with theoretical generic input/output (I/O) card failure, could lead to misleading data on display units and by development of modifications that fix that weak point in the avionics architecture. The FAA is issuing this AD to address misleading data on display units. The unsafe condition, if not addressed, could reduce safety margins and lead to increased pilot workload, possibly resulting in reduced controllability of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0003R1.

(h) Exceptions to EASA AD 2023–0003R1

(1) Where EASA AD 2023–0003R1 refers to September 6, 2021 (the effective of EASA AD 2021–0197), this AD requires using September 1, 2022 (the effective date of AD 2022–12–10).

(2) Where EASA AD 2023–0003R1 refers to July 26, 2022 (the effective date of EASA AD 2022–0145, dated July 12, 2022), and January 20, 2023 (the effective date of EASA AD 2023–0003, dated January 6, 2023), this AD requires using the effective date of this AD.

(3) Where paragraph (1) of EASA AD 2023–0003R1 requires operators to “inform all flight crews, and, thereafter, ensure that each pilot has performed the training and operates the aeroplane accordingly,” and paragraph (2.2) of EASA AD 2023–0003R1 requires operators to “inform all flight crews, and, thereafter, operate the aeroplane accordingly,” this AD does not require those actions as those actions are already required by existing FAA operating regulations (see 14 CFR 91.9, 91.505, 121.137, and 121.628(a)(2) and (5)).

(4) Where paragraph (1.3) of EASA AD 2023–0003R1 specifies to “Implement the instructions of the MMEL–CP”, this AD requires replacing that text with “Revise the operator’s existing FAA-approved minimum equipment list (MEL) to incorporate that information (“the MMEL–CP” as specified in EASA AD 2023–0003R1)”.

(5) Paragraph (1.4) of EASA AD 2023–0003R1 does not apply to this AD.

(6) This AD does not adopt the “Remarks” section of EASA AD 2023–0003R1.

(i) Airplane Flight Manual (AFM) Revision

Within 2 months after September 1, 2022 (the effective date of AD 2022–12–10), revise the applicable existing AFM to incorporate the information specified in figure 1 to paragraph (i) of this AD after sub-sub-section 2–200–70, Emergency Procedures, ADS with IRS miscompare, of sub-section 2–200, Emergency Procedures, of Section 2—Emergency Procedures.

BILLING CODE 4910–13–P

Figure 1 to Paragraph (i)—Training Areas of Special Emphasis for Pilot (TASEp) Tp–118–EZII Info for AFM

TASEp Tp-118-EZII Information

- 1) Potentially unreliable information exists on the iPFD and/or HUD
- 2) Aircraft must be flown by reference to SFD
- 3) Aircraft trajectory must be monitored on the iNAV
- 4) The iNAV may have misleading/confusing representations
- 5) Before using iNAV for aircraft trajectory monitoring, LH pilot side is to be selected
- 6) Pilot side selection has impacts on task sharing between Pilot Flying and Pilot Monitoring
- 7) Presence of both ADS and IRS CAS messages requires that newly developed single emergency procedure must be performed instead of performing separate ADS and IRS emergency procedures
- 8) There may be a time delay of up to 10 secs between the ADS and IRS MISCOMPARE messages during critical phases of flight
- 9) The special single emergency procedure is not available on ECL (paper checklist from AFM or CODDE2 is required)
- 10) Crew workload in this failure situation will be high

BILLING CODE 4910-13-C

(j) No Reporting Requirement

Although the material referenced in EASA AD 2023-0003R1 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(k) Additional AD Provisions

The following provisions also apply to this AD:

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

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions

from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Additional Information

For more information about this AD, contact William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516-228-7301; email: 9-AVS-AIR-BACO-COS@faa.gov.

(m) 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 this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023-0003R1, dated September 26, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3,

50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

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

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

Issued on October 31, 2025.

Steven W. Thompson,

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

[FR Doc. 2025-21480 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-13-P

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

[Docket No. FAA–2025–0912; Project Identifier MCAI–2024–00571–T; Amendment 39–23178; AD 2025–22–01]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A350–941 and –1041 airplanes. This AD was prompted by reports of mechanical noises originating from the nose landing gear (NLG) shock absorber during ground maneuvers. This AD requires repetitive inspections (*i.e.*, steering checks) of the NLG shock absorber and applicable on-condition actions. This AD also limits the installation of affected parts under certain conditions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0912; 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, the mandatory continuing airworthiness information (MCAI), 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.

Material Incorporated by Reference:

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

- 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](https://www.regulations.gov) under Docket No. FAA–2025–0912.

FOR FURTHER INFORMATION CONTACT: Stefanie Roesli, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3964; email: stefanie.n.roesli@faa.gov.

SUPPLEMENTARY INFORMATION:**Background**

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A350–941 and –1041 airplanes. The NPRM was published in the **Federal Register** on May 21, 2025 (90 FR 21702). The NPRM was prompted by AD 2025–0093, dated April 24, 2025 (EASA AD 2025–0093) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI reports instances of mechanical noises originating from the NLG shock absorber during ground maneuvers. Further analysis traced these noises to higher than expected friction between the lower bearing carrier (LBC) and the main fitting of the sliding tube. This friction may cause deformation of the LBC’s anti-rotation tabs, leading to relative movement between the LBC and the main fitting. As a result, wear on the corrosion protection coating of the main fitting may occur due to subsequent movement of the retainer ring positioned between these components, which could lead to corrosion of the NLG main fitting.

In the NPRM, the FAA proposed to require repetitive inspections (*i.e.*, steering checks) of the NLG shock absorber and applicable on-condition actions and limit the installation of affected parts under certain conditions, as specified in EASA AD 2025–0093. The FAA is issuing this AD to address higher than expected friction on the NLG shock absorber LBC, which could result in deformation of the LBC’s anti-rotation tabs and consequent corrosion of the NLG main fitting. The unsafe condition, if not addressed, could lead to structural failure of the NLG, which may result in damage to the airplane and injury to occupants.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0912.

Discussion of Final Airworthiness Directive**Comments**

The FAA received a comment from the Air Line Pilots Association,

International (ALPA) who supported the NPRM without change.

The FAA received additional comments from Delta Air Lines (Delta). The following presents those comments and the FAA’s responses.

Request To Clarify if a Certain Service Bulletin Provides Terminating Action

Delta requested the FAA clarify whether modifications performed using Liebherr Service Bulletin 6407A–32–01, dated May 27, 2025, and any future service bulletin modifications may be used as terminating action for the requirements of the proposed AD. Delta noted that the Liebherr service bulletin provides instructions for modifying certain affected parts to not affected parts, which effectively changes a Group 1 or 3 airplane to a Group 4 airplane. Delta noted that EASA AD 2025–0093 specifies Group 4 airplanes are only subject to the parts prohibition requirement. Delta asserted that the intent of the affected part, not affected part, and group definitions is to allow retrofit of an airplane to become a Group 4 airplane once a modification is developed, such as the one in the Liebherr service bulletin. Delta also asked whether other methods, such as other Airbus service bulletins or replacement of a NLG assembly with one that does not have affected parts installed, could similarly be used to convert a Groups 1 through 3 airplane to a Group 4 airplane.

The FAA acknowledges that if an “Affected part” is replaced with a “Not affected part,” then the airplane would become a Group 4 airplane per the definitions in EASA AD 2025–0093 and the repetitive checks and reporting would no longer need to be accomplished for that airplane. However, the FAA has not received or reviewed Liebherr Service Bulletin 6407A–32–01 to determine if accomplishing the modification in that service bulletin is acceptable as a terminating action for the repetitive checks and reporting required by this AD. Further, the FAA has not received, reviewed, or approved any other service information that would potentially provide a terminating action. Therefore, the FAA declines to revise this AD to allow the Liebherr service bulletin as a terminating action. However, under the provisions of paragraph (i)(1) of this AD, an operator may propose terminating action as an alternative method of compliance (AMOC) for the requirements of this AD. If sufficient substantiating data is provided and an equivalent level of safety is demonstrated, the FAA may approve such AMOC requests to allow for

termination of the required actions in this AD. The FAA has not changed the AD in response to this comment.

Request To Remove Reporting Requirement

Delta requested the FAA add a paragraph to the proposed AD stating that the reporting requirement specified in paragraph (5) of EASA AD 2025–0093 is not adopted. Delta reasoned that reporting is not necessary since Airbus does not need to collect additional data to determine the root cause or final solution because EASA AD 2025–0093 already identifies a final solution in the “Not affected part” definition; and that such parts can be installed in service using Liebherr Service Bulletin 6407A–32–01, dated May 27, 2025. Delta also reasoned reporting is not necessary because there is no list of bad serial numbers, so Airbus does not need to maintain a bad parts pool. Delta concluded that, while Airbus may want operators to continue reporting to assist with tracking spare parts, the reporting requirement does not appear to contribute to an enhanced level of safety.

The FAA disagrees with removing the reporting requirement from this AD. The FAA notes that reporting is required only if there is a discrepancy as specified in paragraph (5) of EASA AD 2025–0093. Although the EASA AD identifies “not affected” parts, the EASA AD does not indicate that a final fix or permanent solution has been developed. Further, the FAA has received no information indicating that Airbus has established a terminating action at this time. Therefore, the FAA considers the reporting requirement necessary to continue gathering data relevant to the unsafe condition. However, the FAA has added a new paragraph (h)(4) to this AD to provide a 30-day grace period for operators who may have accomplished the steering check before the effective date of the AD.

Request To Clarify Which Instructions Are Required for Compliance

Delta requested the FAA clarify which portions of Airbus Alert Operators Transmission (AOT) A32P031–24, Revision 04, dated March 11, 2025, are required for compliance with the proposed AD. Delta noted the AOT indicates section 5.6, including the flowchart, is labeled as required for compliance (RC). Delta also noted EASA AD 2025–0093 specifies accomplishing a steering check of the affected part and applicable corrective actions in

accordance with the instructions of the AOT. Delta interprets this to mean that only the portions of the AOT related to the steering check and corrective actions are required. Delta expressed concern with the first question in the flowchart, which asks whether the NLG secondary seal was activated before installation. Delta stated this question cannot reliably be answered because the mechanic inspecting the NLG will have no knowledge, and there might be no maintenance record, of why the seal was changed. Delta asserted that, if the flowchart is required, the AOT should include a procedure for this question to determine why the seal was changed. Delta also expressed concern with the instruction in the flowchart to replace the NLG shock absorber dynamic seals per a certain maintenance plan task within the compliance time of the AOT. Delta asserted that the AOT does not specify the compliance time for this action. Delta stated that if the flowchart is RC, then the proposed AD should be revised to include a procedure to determine why the secondary seal was activated and a compliance time for replacement of the NLG shock absorber dynamic seals.

The FAA notes that the flowchart in section 5.6 of the AOT is RC. Paragraph (g) of this AD mandates compliance with all required actions and compliance times specified in, and in accordance with, the EASA AD, which in turn references the AOT. Therefore, all sections of the AOT that are labeled as RC, including the flowchart in section 5.6, are required for compliance with this AD.

The FAA acknowledges the commenter’s concern about assessing the cause of secondary seal activation but disagrees with revising this AD to add a procedure to address it. The FAA considers it reasonable to expect operators to determine, through maintenance record review, whether the activation was due to primary seal leakage or another reason. The FAA notes that operators are required to maintain adequate records (per 14 CFR 91.417) to make such determinations and apply the flowchart accordingly.

Regarding the compliance time in the flowchart related to replacement of the NLG shock absorber dynamic seals, the compliance times specified in this AD take precedence. Specifically, the dynamic seal replacement must be completed within the compliance time established for the initial steering check. The FAA has not changed the AD in this regard.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. 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, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025–0093, which specifies procedures for repetitive inspections (*i.e.*, steering checks) for relative movement between the LBC and the main fitting and applicable on-condition actions. The on-condition actions include activating the secondary seal, inspecting and applying torque to the nose landing gear seal changeover valve, inspecting the ring groove for corrosion, and repairing any corrosion. EASA AD 2025–0093 also specifies reporting the results of each check where a discrepancy was identified to the manufacturer and limits the installation of affected parts, for airplanes with an affected part installed, unless the steering check has been completed. For airplanes that do not have an affected part installed, EASA AD 2025–0093 prohibits installing an affected part.

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.

Interim Action

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

Costs of Compliance

The FAA estimates that this AD affects 33 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	Up to 4 work-hours × \$85 per hour = \$340 per inspection cycle.	\$0	Up to \$340 per inspection cycle.	Up to \$11,220 per inspection cycle.

The FAA estimates the following costs to do any on-condition actions that would be required based on the results of the inspections. The FAA has no way of determining the number of aircraft that might need these actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Action	Labor cost	Parts cost	Cost per product
Corrective actions	Up to 11 work-hours × \$85 per hour = \$935	Up to \$2,000	Up to \$2,935.
Reporting	1 work-hour × \$85 per hour = \$85	\$0	\$85.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 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. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

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:

2025–22–01 Airbus SAS: Amendment 39–23178; Docket No. FAA–2025–0912; Project Identifier MCAI–2024–00571–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 2, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by reports of higher than expected friction on the nose landing gear (NLG) shock absorber lower bearing carrier (LBC), which could result in deformation of the LBC's anti-rotation tabs and consequent corrosion of the NLG main fitting. The unsafe condition, if not addressed, could lead to structural failure of the NLG, which could result in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2025–0093, dated April 24, 2025 (EASA AD 2025–0093).

(h) Exceptions to EASA AD 2025–0093

(1) Where EASA AD 2025–0093 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2025–0093 refers to October 4, 2024 (the effective date of EASA AD 2024–0188), this AD requires using the effective date of this AD.

(3) Where paragraph (2) of EASA AD 2025–0093 specifies “within the compliance time(s) specified therein”, this AD requires

replacing that text with “before further flight”.

(4) Paragraph (5) of EASA AD 2025–0093 specifies to report inspection results to Airbus within a certain compliance time. For this AD, report inspection results at the applicable time specified in paragraph (4)(i) or (ii) of this AD.

(i) If the steering check was done on or after the effective date of this AD: Submit the report within 30 days after the steering check.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(5) This AD does not adopt the “Remarks” section of EASA AD 2025–0093.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: 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 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: Except as required by paragraph (i)(2) of this AD, if any material referenced in EASA AD 2025–0093 contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under an RC paragraph, must be done to comply with this AD; any paragraphs, including subparagraphs under those paragraphs, that are not identified as RC are recommended. The instructions in paragraphs, including subparagraphs under those paragraphs, not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the instructions identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to instructions identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Stefanie Roesli, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3964; email: stefanie.n.roesli@faa.gov.

(k) 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 this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2025–0093, dated April 24, 2025.

(ii) [Reserved]

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

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

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

Issued on October 27, 2025.

Lona C. Saccomando,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–21479 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–0739; Project Identifier AD–2025–00196–T; Amendment 39–23177; AD 2025–21–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 717–200 airplanes. This AD was prompted by a report of a nose landing gear-up landing caused by the failure of the upper lock link assembly. This AD requires repetitive inspections for cracking of the upper lock link assembly and applicable on-condition actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2025–0739; 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.

Material Incorporated by Reference:

- For the Boeing 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.

- 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–2025–0739.

FOR FURTHER INFORMATION CONTACT:

Wayne Ha, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 562–627–5238; email: wayne.ha@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all The Boeing Company Model 717–200 airplanes. The NPRM was published in the **Federal Register** on April 29, 2025 (90 FR 17746). The NPRM was prompted by a report of a nose landing gear-up landing caused by the failure of the upper lock link assembly. In the NPRM, the FAA proposed to require repetitive inspections for cracking of the upper lock link assembly and applicable on-condition actions. The FAA is issuing this AD to address a failure of the upper lock link assembly caused by non-conforming surface roughness, due to tool marks on the surface. The unsafe condition, if not addressed, could result in a failure of the nose landing gear (NLG) to fully extend during landing or cause the nose gear to remain retracted while the main gear deploys. Additionally, it could restrict ground

maneuverability, increasing the risk of a runway excursion.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA) and Boeing who supported the NPRM without change.

The FAA received additional comments from Delta Air Lines (Delta) and an anonymous commenter. The following presents those comments and the FAA's response.

Request To Exclude Newly Manufactured Parts

Delta requested that the FAA add an exception to paragraph (h) of the proposed AD to exclude from the overhaul requirement upper lock link assemblies manufactured after a specific date. Delta stated that Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, specifies overhauling all upper lock link assemblies, including newly manufactured parts. Delta claimed that overhaul of new parts places a significant burden on operators, particularly those relying on third-party vendors for overhaul services. Delta also expressed concern that this action implies newly manufactured parts are still being manufactured and delivered with the known defect. However, if the part defect has been addressed in production, Delta stated new parts produced after a specific date determined by the manufacturer should be exempted from the overhaul requirement.

The FAA acknowledges the request. After consultation with the parts manufacturer, the FAA has determined that upper lock link assemblies manufactured after December 31, 2001, are serviceable upper lock link assemblies and therefore should be exempt from the overhaul requirement. Accordingly, the FAA has added paragraphs (h)(2) and (3) of this AD to exclude airplanes with an upper lock link assembly manufactured after December 31, 2001, from the requirements of this AD.

Request To Expand the Definition of Serviceable Upper Lock Link Assembly

Delta requested that the FAA add an exception to paragraph (h) of the proposed AD to expand the definition of a serviceable upper lock link assembly to include parts that were manufactured after a specific date determined by the manufacturer. As discussed in the previous comment, Delta stated that the part defect may have been addressed in

production, and these new parts should be included in the definition of a serviceable upper lock link assembly. Delta stated that note (a) of table 1 defines a serviceable part solely as one that has been overhauled in accordance with a certain overhaul manual.

The FAA agrees with the request for the reasons provided in the previous comment. Accordingly, the FAA has added paragraph (h)(4) to include upper lock link assemblies manufactured after December 31, 2001, in the definition of a serviceable upper lock link assembly.

Request To Allow Installation of a Non-Overhauled Part

Delta noted that table 1, condition 1 of Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, specifies installing a serviceable upper lock link assembly (*i.e.*, one that has been overhauled in accordance with a certain overhaul manual) before further flight if any crack is found as a result of the eddy current high frequency (ETHF) inspection. Delta requested the FAA add an exception to paragraph (h) of the proposed AD to provide an option to table 1, condition 1 (in case a crack is found) that instead allows installation of an upper lock link assembly that has not been overhauled in accordance with a certain overhaul manual but has complied with the initial ETHF inspection. Delta suggested that an upper lock link assembly that has been inspected by the ETHF inspection should be considered acceptable for installation because it is being tracked to comply with the repetitive inspection interval every 4,800 flight cycles. Delta asserted that this approach would maintain an equivalent level of safety while offering operators greater flexibility.

The FAA infers that Delta is requesting that the FAA revise the AD to allow installation of an upper lock link assembly that has not been overhauled in accordance with the overhaul manual referenced in the requirements bulletin but on which the ETHF inspection has been accomplished with no crack found. The FAA agrees with this request. The FAA has determined that, in this case, the affected upper lock link assembly is being tracked and maintained in accordance with the required repetitive ETHF inspection interval, and that this approach maintains an equivalent level of safety. The FAA has not changed the AD in this regard because installation of a non-overhauled part is already acceptable under table 1, condition 2, option 1 of the requirements bulletin.

Request To Reduce the Repetitive Inspection Interval

An anonymous commenter requested that the FAA revise the proposed AD to require more frequent inspections, especially for aircraft with high cycle counts. The commenter asserted that the proposed inspection requirements do not address the serious safety risk of the nose gear-up landing incident that prompted the proposed AD.

The FAA disagrees with reducing the repetitive inspection interval. The safety concern of this AD is not related to the number of airplane cycles. The root cause of the upper lock link assembly failure was non-conforming surface roughness from tool marks. The referenced service information in this AD outlines procedures for repetitive ETHF inspections of both the top and bottom surfaces of the upper lock link assembly to detect any cracks and specifies replacement of any cracked assemblies with serviceable ones. The repetitive inspection interval of 4,800 cycles was calculated by crack growth analysis and was correlated to the striation count data in the National Transportation Safety Board (NTSB) lab report. The required inspection interval allows for two inspection opportunities between crack detectability and instability. The FAA did not change this AD in response to this comment.

Request To Require Immediate Replacement of the Affected Parts

An anonymous commenter requested that the FAA revise the proposed AD to require immediate replacement of all upper lock link assemblies manufactured during the same production period as the failed part identified in the related NTSB report, rather than waiting for cracks to become visible during routine inspections.

The FAA disagrees with the request. As discussed in its response to the previous comment, the FAA has determined that accomplishing the repetitive inspections within the required inspection interval provides an acceptable level of safety. Replacement of the upper lock link assemblies with a serviceable upper lock link assembly terminates the repetitive inspections. The FAA notes that a serviceable upper lock link assembly is defined in Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, except as specified in paragraph (h)(4) of this AD. The FAA has not changed the AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered the 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, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51
The FAA reviewed Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025. This material specifies procedures for repetitive ETHF inspections of the top and bottom surfaces of the upper lock link assembly for any crack, and replacement of any cracked upper lock link assembly with a serviceable upper lock link assembly. This material also specifies that replacement of the upper

lock link assembly terminates the repetitive inspections.
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.
Costs of Compliance
The FAA estimates that this AD affects 117 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS				
Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
ETHF inspection ..	5 work-hours × \$85 per hour = \$425 per inspection cycle.	\$0	\$425 per inspection cycle	\$49,725 per inspection cycle.

The FAA estimates the following costs to do any necessary replacement that would be required based on the results of the inspection. The agency has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS			
Action	Labor cost	Parts cost	Cost per product
Replacement	9 work-hours × \$85 per hour = \$765	\$17,819	\$18,584

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:
2025–21–05 The Boeing Company:
Amendment 39–23177; Docket No. FAA–2025–0739; Project Identifier AD–2025–00196–T.
(a) Effective Date
This airworthiness directive (AD) is effective January 2, 2026.
(b) Affected ADs
None.
(c) Applicability
This AD applies to all The Boeing Company Model 717–200 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025.
(d) Subject
Air Transport Association (ATA) of America Code 32, Landing Gear.
(e) Unsafe Condition
This AD was prompted by a report of a Boeing Model 717–200 operator that experienced a nose landing gear-up landing caused by the failure of the upper lock link assembly. The unsafe condition, if not addressed, could result in a failure of the nose landing gear (NLG) to fully extend during landing or cause the nose gear to remain retracted while the main gear

deploys. Additionally, it could restrict ground maneuverability, increasing the risk of a runway excursion.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the "Compliance" paragraph of Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 717–32A0043, dated February 12, 2025, which is referred to in Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025.

(h) Exceptions to Requirements Bulletin Specifications

(1) Where the Condition and Compliance Time columns of the tables in the "Compliance" paragraph of Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, refer to the original issue date of Requirements Bulletin 717–32A0043 RB, this AD requires using the effective date of this AD.

(2) Where the Condition column of table 1 in the "Compliance" and "Accomplishment Instructions" paragraphs of Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, specifies all airplanes with an Upper Lock Link assembly that has not been overhauled, as of the Original Issue date of Requirements Bulletin 717–32A0043 RB, in accordance with OHM 32–21–2, Revision No. 63 dated July 01, 2024, or later Boeing approved revisions published on New Maintenance Performance Toolbox (nMPT), that condition does not apply to an Upper Lock Link assembly that was manufactured after December 31, 2001.

(3) Where the Condition column of table 1 in the "Compliance" and "Accomplishment Instructions" paragraphs of Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, specifies "All airplanes with an Upper Lock Link assembly that has been overhauled", this AD requires replacing that text with "All airplanes with an Upper Lock Link assembly that was manufactured after December 31, 2001, or has been overhauled".

(4) Where note (a) of table 1 in the "Compliance" and "Accomplishment Instructions" paragraphs of Boeing Alert Requirements Bulletin 717–32A0043 RB, dated February 12, 2025, defines a serviceable Upper Lock Link assembly as "one that has been overhauled", this AD requires replacing that text with "one that was manufactured after December 31, 2001, or that has been overhauled".

(i) 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 (j)(1) of this AD. Information may be emailed to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) 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.

(j) Related Information

(1) For more information about this AD, contact Wayne Ha, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 562–627–5238; email: *wayne.ha@faa.gov*.

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (k)(3) this AD.

(k) 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 717–32A0043 RB, dated February 12, 2025.

(ii) [Reserved]

(3) For the Boeing 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 October 17, 2025.

Lona C. Saccomando,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–21478 Filed 11–26–25; 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; Amendment 39–23174; AD 2025–21–02]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–15–06, which applied to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes. AD 2022–15–06 required 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 AD continues to require the actions specified in AD 2022–15–06 and requires those actions for additional connectors. This AD also requires determining if affected transorb modules are installed, replacing or testing affected transorb modules, and applicable on-condition actions. This AD also prohibits the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2026.

ADDRESSES:

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 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.

Material Incorporated by Reference:

- For Boeing 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.

- 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:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2022–15–06, Amendment 39–22126 (87 FR 47334, August 3, 2022) (AD 2022–15–06). AD 2022–15–06 applied to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes. The NPRM was published in the **Federal Register** on September 26, 2024 (89 FR 78827). The NPRM was prompted by the determination that connectors that were not identified in AD 2022–15–06 are affected and by the development of a replacement action to address the unsafe condition, which would terminate the existing actions. In the NPRM, the FAA proposed to continue to require the actions specified in AD 2022–15–06 and require those actions for additional connectors. The NPRM also proposed to require determining if affected transorb modules are installed, replacing or testing affected transorb modules, and applicable on-condition actions. The NPRM also proposed to prohibit the installation of affected parts. The NPRM 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.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from Air Line Pilots Association, International (ALPA), and Cathay Pacific, who supported the NPRM without change.

The FAA received additional comments from five commenters, including American Airlines, Boeing, FedEx Express, and United Airlines (United). The following presents the comments received on the NPRM and the FAA’s response to each comment.

Request To Revise the Applicability

Boeing requested that paragraph (c) of the proposed AD be revised to limit the applicability to the airplanes affected by Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023. Boeing stated that if the AD applies to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes (including the airplanes after line number 1726—the airplanes that will have this change already incorporated in production), then the airplanes delivered after the effective date of this AD would need to document that these AD actions were incorporated in production in an AD Letter (ADL), stating that the airplane is not affected by the AD.

The FAA disagrees with Boeing’s request that paragraph (c) of this AD be revised because the transorbs are rotatable and these parts could later be installed on airplanes that were initially delivered with acceptable parts, thereby subjecting those airplanes to the unsafe condition. All airplanes are subject to the parts installation prohibition specified in paragraph (k) of this AD, which does not allow affected parts to be installed as of the effective date of the AD.

The FAA notes that airplanes produced after the effective date of this AD do not need to document that the actions in Boeing Alert Requirements Bulletin 777–27A0125 RB, dated February 3, 2023, were done because paragraphs (i)(1) and (2) of this AD only apply to airplanes produced on or before the effective date of this AD. Additionally, the FAA has revised paragraphs (g) and (h) of this AD to limit those requirements to airplanes

produced on or before the effective date of this AD since airplanes produced after the effective date of this AD will not be delivered with the affected transorb modules or connectors.

Request To Allow Optional Action to the Replacement of Required Actions

FedEx Express requested that the FAA revise paragraph (i)(2) of the proposed AD to allow continued flight with the GSS connectors stowed per paragraphs (g) and (h) of the proposed AD, as an optional action. The commenter stated that the reactivation in paragraph (i)(2) of the proposed AD does not appear to lend any effort towards airworthiness of the aircraft outside of passenger comfort. Additionally, the commenter noted that such a system is not a requirement of 14 CFR part 25 and therefore expenditure of valuable time and resources on a system not appreciably utilized by a cargo carrier would seem pointless.

The FAA acknowledges the commenter’s request. The purpose of this AD is to restore the affected fleet to an acceptable level of safety. 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 and could result in loss of control of the airplane. Allowing the connectors to be disconnected long-term may not address the unsafe condition in the affected fleet, as an operator may inadvertently reconnect the affected connectors in the future. Therefore, the replacement of affected connectors must be done to address the unsafe condition. However, any person may request approval of an alternative method of compliance (AMOC) under the provisions of paragraph (l)(2) of this AD. This AD has not been changed regarding this request.

Request for Removing/Revising Paragraphs (g) and (h) of the Proposed AD and References to Connector D02099P

Boeing requested that the FAA remove paragraph (h) of the proposed AD, update paragraph (g) of the proposed AD by referring to bundle/connector W6313/D02098P, and remove references to connector D02099P from “Actions Since AD–2022–15–06 Was Issued” in the NPRM. Boeing suggested some revised wording for paragraph (g) of the proposed AD to account for additional wire to bundles/connector part numbers that are present on some

airplanes. Boeing stated paragraph (h) of the proposed AD could be misleading to operators as it does not highlight that the difference in the bundle and connector callouts are line number dependent. In addition, Boeing stated the connectors called out in paragraph (h) of the proposed AD are incorrect and reference two disconnect points on the same wire bundle. Boeing recommended that connector D02099P not be referenced as a disconnect point in the NPRM.

United requested that the FAA revise paragraph (h) of the proposed AD to allow for disconnecting one of the connectors rather than the referenced “W6313/D02098P and W7314/D02099P,” which would require operators to unnecessarily disconnect both. United stated that the connectors are in the same wiring circuit so disconnecting either connector D02098P or D02099P would effectively deactivate the upper gust suppression transducer circuit. United noted it has disconnected, capped, and stowed connector D02099P and connector D02098P remains connected for these aircraft as allowed in AMOC letter 783–22–11124, dated January 17, 2023.

American Airlines requested that the FAA change references to wire bundles/connectors from “W6313/D02098P and W7314/D02099P” to “W6313/D02098P or W7314/D02099P,” as disconnecting either from the transorb module sufficiently complies with the level of safety required by the proposed AD.

The FAA agrees with rewording paragraph (h) of this AD to address the

two disconnect points of the wire bundles being referenced as “W6313/D02098P and W7314/D02099P” to “W6313/D02098P or W7314/D02099P” to alleviate confusion of referencing disconnecting both from the transorb module; the disconnection of either bundle/connector provides an equivalent level of safety. Paragraph (h) of this AD has been updated to the reference above.

The FAA disagrees with removing paragraph (h) of this AD and updating paragraph (g) of this AD because either bundles/connectors W6313/D02098P or W7314/D02099P can be disconnected to address the unsafe condition. This AD has not been changed to remove the actions required by paragraph (h) of this AD.

Regarding the request to revise the wording in paragraph (g) of this AD, the FAA agrees to clarify. AMOC letter 783–22–11124, dated January 17, 2023, allows operators to use the wording suggested by Boeing. Paragraph (l)(4) of this AD allows operators to use AMOCs previously approved for AD 2022–15–06 for the corresponding provisions of paragraph (g) of this AD. Therefore, no change to this AD is necessary.

Regarding the request to revise “Actions Since AD–2022–15–06 Was Issued” in the NPRM, that language is not restated in this final rule; however, the FAA acknowledges that the text should have stated “disconnect the connectors and cap and stow the wires to bundles/connectors W6313/D02098P or W7314/D02099P.”

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, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

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.

Costs of Compliance

The FAA estimates that this AD affects 312 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
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 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 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 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 AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (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:
 - a. Removing Airworthiness Directive (AD) 2022–15–06, Amendment 39–22126 (87 FR 47334, August 3, 2022); and
 - b. Adding the following new AD:

2025–21–02 The Boeing Company:
Amendment 39–23174; Docket No. FAA–2024–2144; Project Identifier AD–2024–00424–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 2, 2026.

(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 Revised Affected Airplanes

For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD: This paragraph restates the requirements of paragraph (g) of AD 2022–15–06, with revised affected airplanes. 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, CLPT–12SP–07, and CLPT–12SP–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

For airplanes with an 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 paragraphs (h)(1) and (2) of this AD: Disconnect the connectors and cap and stow the wires to bundles/connectors W6313/D02098P or W7314/D02099P from the transorb module part numbers CLPT–12SP–06, CLPT–12SP–07, and CLPT–12SP–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 an 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, CLPT–12SP–07, or CLPT–12SP–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 airworthiness certificate 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, CLPT–12SP–07, or CLPT–12SP–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 October 7, 2025.

Lona C. Saccomando,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–21477 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–0479; Project Identifier MCAI–2024–00436–T; Amendment 39–23172; AD 2025–20–19]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2016–14–03, which applied to all Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2016–14–03 required reinforcing the forward pressure bulkhead at a certain stringer on both the left-hand and right-hand sides and doing related investigative and corrective actions if necessary. Since the FAA issued AD 2016–14–03, new crack findings have

prompted the need for repetitive inspections of the area. This AD continues to require the actions in AD 2016–14–03, adds repetitive inspections of structure at a certain frame and applicable corrective actions, provides a terminating action for the repetitive inspections, and revises the applicability by removing airplanes and adding certain airplane models. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2025–0479; 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, the mandatory continuing airworthiness information (MCAI), 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.

Material Incorporated by Reference:

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

- 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–2025–0479.

FOR FURTHER INFORMATION CONTACT:

Nicholas Benson, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3647; email: nicholas.h.benson@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2016–14–03, Amendment 39–18584 (81 FR 44496, July 8, 2016) (AD 2016–14–03). AD 2016–14–03 applied to all Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes;

Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2016–14–03 required reinforcing the forward pressure bulkhead at a certain stringer on both the left-hand and right-hand sides and doing related investigative and corrective actions if necessary. The FAA issued AD 2016–14–03 to prevent fatigue cracking of the forward pressure bulkhead, which could result in reduced structural integrity of the airplane.

The NPRM was published in the **Federal Register** on March 27, 2025 (90 FR 13848). The NPRM was prompted by AD 2024–0147R1, dated August 7, 2024 (EASA AD 2024–0147R1) (also referred to as “the MCAI”), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that after EASA AD 2014–0209 was issued, several findings of cracks were reported in service during application of Airworthiness Limitation Item (ALI) tasks 532166 and 533186. As a result of these findings, Airbus has developed different thresholds and inspection requirements compared to those specified in ALI tasks 532166 and 533186 and requires those inspections until a modification is done.

In the NPRM, the FAA proposed to continue to require the actions in AD 2016–14–03. The FAA also proposed to add repetitive inspections of structure at a certain frame and applicable corrective actions, provide a terminating action for the repetitive inspections, and revise the applicability by removing airplanes and adding certain airplane models, as specified in EASA AD 2024–0147R1. The FAA is issuing this AD to address the unsafe condition on these airplane products.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0479.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from United Airlines who supported the NPRM without change.

The FAA received additional comments from American Airlines (American), Delta Air Lines (Delta), and ProTech Aero Services Limited (ProTech). The following presents the comments received on the NPRM and the FAA’s response to each comment.

Request To Confirm Use of Later Revisions Is Allowed

ProTech requested the FAA confirm that the proposed AD would allow the

use of later-approved revisions of the material specified in EASA AD 2024–0147R1, as acceptable for compliance with the AD requirements.

This AD does allow the use of later-approved revisions of the material referenced in EASA AD 2024–0147R1 as acceptable for compliance with the required actions. This AD adopts the “Ref. Publications” section of EASA AD 2024–0147R1, which includes the current version of the referenced material as well as later approved revisions.

Request To Provide Credit for Actions Accomplished per a Certain Service Bulletin

Delta requested the FAA confirm that accomplishment of Airbus Service Bulletin A320–53–1372, dated May 15, 2018, instead of Airbus Service Bulletin A320–53–1268, Revision 03, dated May 7, 2015, suffices for taking credit for paragraph (4) of EASA AD 2024–0147R1. If the FAA agrees, then Delta requested the FAA add a new exception to paragraph (h) of the proposed AD to specify, where paragraph (4) of EASA AD 2024–0147R1 states “in accordance with the instructions of Airbus Service Bulletin A320–53–1268,” this AD considers Airbus Service Bulletin A320–53–1372 as acceptable for compliance. Delta requested the new exception because paragraph (4) of the EASA AD 2024–0147R1 does not mention Airbus Service Bulletin A320–53–1372, and the FAA’s NPRM does not address Delta’s concern. Delta stated it received an acceptable method of compliance (AMOC) to FAA AD 2016–14–03 (via AMOC Letter No. AIR–676–18–307, dated July 20, 2018) that allowed use of Airbus Service Bulletin A320–53–1372 instead of Airbus Service Bulletin A320–53–1268 and would like to take credit for previous compliance actions for its applicable airplanes.

The FAA partially agrees. The FAA agrees that, for certain airplane serial numbers, the modification specified in paragraph (3) of EASA AD 2024–0147R1 may be accomplished using the original issue of Airbus Service Bulletin A320–53–1372, dated May 15, 2018, or later approved revisions, but disagrees that an exception is needed to provide credit for accomplishing the modification using the original issue of that service bulletin before the effective date of this AD. EASA AD 2024–0147R1 defines “the applicable modification SB” as Airbus Service Bulletin A320–53–1268, Revision 01, or Airbus Service Bulletin A320–53–1372, as applicable to the manufacturer serial number. Since no revision number is cited for Airbus

Service Bulletin A320–53–1372 in the definition, this means operators may use any revision of the service bulletin specified in the “Ref. Publications” paragraph of the EASA AD, as applicable, to accomplish the modification. However, paragraph (4) of EASA AD 2024–0147R1 is necessary to provide credit for any modification done before the effective date of this AD using the original issue of Airbus Service Bulletin A320–53–1268, dated January 8, 2013, because the definition only cites Revision 01 of that service bulletin. The FAA has not changed the AD in this regard.

The FAA clarifies that AMOCs approved previously for AD 2016–14–03 are approved as AMOCs for the corresponding provisions of EASA AD 2024–0147R1 that are required by paragraph (g) of this AD. The FAA has revised paragraph (i) of this AD accordingly.

Request To Correct Part Numbers

American requested the FAA revise the proposed AD to allow use of the correct part numbers as an AMOC to certain part numbers specified in Figure A–GBAAG—Sheet 02 of Airbus Service Bulletin A320–53–1383, dated March 5, 2019. American stated that, while incorporating changes found in Airbus Service Bulletin Information Transmission (SBIT) 19–0038, Revision 03, dated February 10, 2025, it found an error in the figure, and Airbus confirmed that certain part numbers in the tables and instructions for COMPD07 of subtasks 531383–420–202–001 and 531383–420–204–001 should be corrected.

The FAA agrees there is an error in Airbus Service Bulletin A320–53–1383, dated March 5, 2019, but no change to this AD is necessary. The FAA reviewed the service bulletin and determined that Figure A–GBAAG Sheet 02 is not required for compliance. Subtasks 531383–420–202–001 and 531383–420–204–001 provide procedures to wet install fasteners in accordance with Structural Repair Manual (SRM) 51–42–00, but they only reference the figure and an airplane maintenance manual (AMM) task for additional information. Since the service bulletin does not specify that the fastener installation must be done in accordance with the figure, operators are not required to use the part numbers identified in the figure. Operators may instead use the correct part numbers identified in Airbus Message 81581889/005, Discrepancy in Figure A–GBAAG Sheet 02, dated April 24, 2025, to comply with the requirements of this AD. Further, Airbus’s response to American

indicated the part numbers would be corrected in a later revision of the service bulletin, which may be used for compliance according to the “Ref. Publications” section of EASA AD 2024–0147R1. The FAA has not changed the AD in this regard.

Request To Correct a Typographical Error

Delta requested the FAA revise the exception in paragraph (h)(4) of the proposed AD by changing “herein” to “therein.” Delta stated paragraph (6) of EASA AD 2024–0147R1 uses “herein” to specify the compliance times for repair instructions provided by Airbus based on inspection findings after accomplishing ALI tasks 532166 and 533186. Delta believes “herein” is a typographical error because the EASA AD does not mention any compliance times for the ALI tasks inspection findings. Delta stated that repair instructions and compliance times as a result of the ALI inspection findings should be specified in the appropriate Airbus Repair Design Approval Forms (RDAFs).

The FAA does not agree that usage of “herein” in EASA AD 2024–0147R1 and paragraph (h)(4) of this AD is a typographical error. Paragraph (6) of the EASA AD applies to airplanes that have been inspected per ALI task 532166 and/or 533186 and repaired using Airbus approved instructions. The FAA clarifies that, for these airplanes, paragraph (6) of the EASA AD specifies accomplishing the repetitive inspections of each repaired hole in accordance with the applicable Airbus approved instructions within the compliance time “herein,” where herein refers to table 1 of the EASA AD for the applicable inspection compliance times. The FAA has not revised the AD in this regard.

Request To Calculate Compliance Time Based on Accomplishment of a Certain Task

Delta requested the FAA add an exception to paragraph (h) of the proposed AD to allow the compliance time in table 1 of EASA AD 2024–0147R1 to be calculated based on accomplishment of ALI task 532166–01–1 instead of ALI task 532166–02–1. Delta noted that ALI task 532166–02–1 states the task is an alternative to ALI task 532166–01–1, and that it accomplishes ALI task 532166–01–1 instead of ALI task 532166–02–1. Since Airbus has stipulated that the task is alternative, Delta therefore concluded that the compliance time may also be calculated using ALI task 532166–01–1 instead of ALI task 532166–02–1.

The FAA does not agree with the request. EASA AD 2024–0147R1 does not list ALI task 532166–01–1 as an alternate inspection task in Table 1—Initial Inspection. Further, ALI task 532166–02–1 is a special detailed inspection (rototest), while ALI task 532166–01–1 is a visual inspection. The FAA has not changed this AD in this regard.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. 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, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0147R1, which specifies procedures for repetitive inspections for cracking of the airplane structure at frame (FR) 35 and stringer (STGR) 30 on the left-hand and right-hand sides for Airbus SAS Model A318, Model A319, and Model A320 airplanes; and at FR 35.8 and STGR 30 on the left-hand and right-hand sides for Airbus SAS Model A321 airplanes. EASA AD 2024–0147R1 also specifies obtaining and following instructions for crack repair. EASA AD 2024–0147R1 specifies that accomplishment of that inspection on an airplane terminates ALI tasks 532166 and task 533186 requirements.

EASA AD 2024–0147R1 also specifies procedures for modifying the forward pressure bulkhead at the frame coupling on the left-hand and right-hand sides of FR 35 and STGR 30, including applicable related investigative and corrective actions, for Airbus SAS Model A318, Model A319, and Model A320 airplanes; and at FR 35.8 and STGR 30 for Airbus SAS Model A321 airplanes. EASA AD 2024–0147R1 specifies that this modification constitutes terminating action for the repetitive inspections for that airplane.

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.

Costs of Compliance

The FAA estimates that this AD affects 1,922 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates that it would take up to 21 work-hours per product to comply with the retained actions from AD 2016–14–03. The average labor rate is \$85 per work-hour. Based on these figures, FAA estimates the cost for U.S. operators is up to \$3,430,770, or up to \$1,785 per product.

The FAA estimates that it would take up to 11 work-hours per product to comply with the new proposed actions. The average labor rate is \$85 per work-hour. Based on these figures, FAA estimates the cost for U.S. operators is up to \$1,797,070, or up to \$935 per product.

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

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

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:
 - a. Removing Airworthiness Directive (AD) 2016–14–03, Amendment 39–18584 (81 FR 44496, July 8, 2016); and
 - b. Adding the following new AD:

2025–20–19 Airbus SAS: Amendment 39–23172; Docket No. FAA–2025–0479; Project Identifier MCAI–2024–00436–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 2, 2026.

(b) Affected ADs

This AD replaces AD 2016–14–03, Amendment 39–18584 (81 FR 44496, July 8, 2016) (AD 2016–14–03).

(c) Applicability

This AD applies to Airbus SAS Model airplanes specified in paragraphs (c)(1) through (4) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2024–0147R1, dated August 7, 2024 (EASA AD 2024–0147R1).

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by the need to complete certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. This AD was also prompted by reports that during inspections accomplished as specified in certain Airworthiness Limitation Items (ALIs), cracks were detected on the fastener holes at frame (FR) 35 or FR 35.8 between stringers (STGRs) 28 and 31. The FAA is issuing this AD to prevent fatigue cracking on the forward pressure bulkhead. The unsafe condition, if not addressed, could result in reduced structural integrity of the fuselage.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0147R1.

(h) Exceptions to EASA AD 2024–0147R1

(1) Where EASA AD 2024–0147R1 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (2) of EASA AD 2024–0147R1 specifies “If, during any inspection as required by paragraph (1) of this AD, discrepancies are detected, before next flight, contact Airbus to obtain approved instructions for corrective action and accomplish those instructions accordingly”, this AD requires replacing that text with the following: “If, during any inspection as required by paragraph (1) of this AD, any cracking is detected, the cracking must be repaired before further flight using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.”

(3) Where EASA AD 2024–0147R1 refers to “03 October 2014 [the effective date of EASA AD 2014–0209],” this AD requires using August 12, 2016 (the effective date of AD 2016–14–03).

(4) Where paragraph (6) of EASA AD 2024–0147R1 specifies “repaired using Airbus approved instructions, accomplish the (repetitive) inspection for each repaired hole in accordance with the applicable Airbus approved instructions within the compliance time herein specified”, this AD requires replacing that text with the following: “repaired using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS’s EASA DOA, provided the DOA approval includes the DOA-authorized signature: accomplish the (repetitive) inspection for each repaired hole in accordance with the applicable approved instructions within the compliance time herein specified.”

(5) This AD does not adopt the “Remarks” section of EASA AD 2024–0147R1.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* 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 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: AMOC@faa.gov.

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

(ii) AMOCs approved previously for AD 2016–14–03 are approved as AMOCs for the corresponding provisions of EASA AD 2024–0147R1 that are required by paragraph (g) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

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

(j) Additional Information

For more information about this AD, contact Nicholas Benson, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3647; email: nicholas.h.benson@faa.gov.

(k) 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 this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0147R1, dated August 7, 2024.

(ii) [Reserved]

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

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

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

Issued on October 3, 2025.

Peter A. White,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025-21476 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2025-0473; Project Identifier AD-2024-00281-T; Amendment 39-23167; AD 2025-20-14]

RIN 2120-AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2018-26-03, which applied to all The Boeing Company Model 757-200 series airplanes. AD 2018-26-03 required, for the Captain's and First Officer's seats, repetitive horizontal actuator identifications, repetitive checks of the horizontal movement system (HMS), a detailed inspection of the HMS, as applicable, and applicable on-condition actions. AD 2018-26-03 also required a general visual inspection to determine the seat part numbers of the Captain's and First Officer's seats, a cable adjustment check on seats with certain seat part numbers, and applicable on-condition actions. This AD was prompted by reports of uncommanded movement of the Captain's and First Officer's seats. This AD retains the requirements of AD 2018-26-03 and adds an inspection for previously omitted part numbers. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2026.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 2, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of January 31, 2019 (83 FR 66612, December 27, 2018).

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA-2025-0473; 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.

Material Incorporated by Reference:

- For Boeing 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.

- 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-2025-0473.

FOR FURTHER INFORMATION CONTACT: Julie Linn, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206-231-3584; email: Julie.Linn@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2018-26-03, Amendment 39-19533 (83 FR 66612, December 27, 2018) (AD 2018-26-03). AD 2018-26-03 applied to all The Boeing Company Model 757-200 series airplanes. The NPRM was published in the **Federal Register** on March 31, 2025 (90 FR 14213). The NPRM was prompted by reports of uncommanded movement of the Captain's and First Officer's seats and the determination that additional seats are affected by the unsafe condition. In the NPRM, the FAA proposed to continue to require the actions in AD 2018-26-03 and add an inspection for previously omitted part numbers. The FAA is issuing this AD to address uncommanded movement of the Captain's and First Officer's seat, which could lead to reduced controllability of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International and ProTech Aero Services Limited who supported the NPRM without change.

The FAA also received comments from Boeing, Delta Air Lines (Delta), and an anonymous commenter. The following presents those comments and the FAA's response.

Request To Clarify Seat Applicability for Acceptable Conditions for Compliance

Delta requested the FAA revise paragraph (m) of the proposed AD to clarify that it applies to an Ipeco Captain's or First Officer's seat currently installed on an airplane. Delta stated that paragraph (m) of the proposed AD could be interpreted as applying to all seats currently installed on an airplane, or seats that were previously modified as required by AD 2018-26-03.

The FAA agrees with the commenter's rationale and has revised paragraph (m) of this AD to specify the paragraph applies to seats installed on an airplane.

Request To Revise the Acceptable Conditions for Compliance

Boeing requested the FAA revise paragraph (m) of this AD to state that, if airplane records show an Ipeco Captain's or First Officer's seat meets either one of two conditions for Boeing Special Attention Service Bulletin 757-25-0308 in table 1 to paragraph (m) of the proposed AD, then the actions in paragraphs (g) and (h), as applicable, of the proposed AD are not required for that seat; and if the records show that a seat meets either one of two conditions for Boeing Special Attention Service Bulletin 757-25-0309 in table 1 to paragraph (m) of the proposed AD, then the actions in paragraphs (j) and (k), as applicable, of the proposed AD are not required for that seat. Boeing stated this change would clarify that accomplishment of either Boeing Special Attention Service Bulletin 757-25-0308 or 757-25-0309 alone does not alleviate both adverse conditions of the seats, and that actions in both service bulletins are necessary. Boeing also stated that one row for Boeing Special Attention Service Bulletin 757-25-0308 must be completed for the HMS issue to satisfy the requirements of paragraphs (g) and (j) of the proposed AD, and one row must be completed for Boeing Special Attention Service Bulletin 757-25-0309 to satisfy the requirements of

paragraphs (h) and (k) of the proposed AD.

The FAA agrees with the intent of the commenter's request and has revised paragraph (m) of this AD to match the language the FAA adopted in other ADs that address the same unsafe condition on other Boeing airplane models. Paragraph (m) of this AD states, in part, if airplane records show a seat installed on an airplane meets the conditions in any of the three rows for Boeing Special Attention Service Bulletin 757-25-0308 in table 1 to paragraph (m) of this AD, then the actions in paragraphs (g) and (j), as applicable, of this AD are not required for that seat; and if the airplane records show a seat installed on an airplane meets the conditions in any of the three rows for Boeing Special Attention Service Bulletin 757-25-0309 in table 1 to paragraph (m) of this AD, then the actions specified in paragraphs (j) and (k), as applicable, of this AD are not required for that seat.

Request To Correct Service Bulletin Reference

Boeing and Delta requested that the FAA correct three references to service bulletin number "777-25-0309" in table 1 to paragraph (m) of the proposed AD. The commenters stated the correct reference is Boeing Special Attention Service Bulletin 757-25-0309.

The FAA agrees and has revised table 1 to paragraph (m) of this AD accordingly.

Request To Add Service Information as Acceptable Conditions for Compliance

Delta requested that the FAA add Ipeco Service Bulletin 258-25-16, Issue 4, dated September 11, 2017; and Issue 5, dated April 29, 2020, to table 1 to paragraph (m) of the proposed AD. Delta stated that these service bulletins embody the HMS inspection and overhaul of the Captain's and First Officer's seats. Delta noted that, under the proposed table, compliance is acceptable (*i.e.*, the actions specified in paragraphs (g), (h), (j), and (k) of the proposed AD are not required) if actions are done in accordance with Boeing Special Attention Service Bulletin 757-25-0308, Revision 1, dated June 7, 2018, and additional actions are done in accordance with Ipeco Service Bulletin 258-25-15, Issue 4, dated February 16, 2018; Issue 5, dated April 29, 2020; or Issue 6, dated November 1, 2021, for Ipeco part number (P/N) 3A258-0007-01-1 or 3A258-0008-01-1 with horizontal actuator Artus P/N AD8650503 at "Amendment C" or later. Delta also noted that Revision 1 of Boeing Special Attention Service Bulletin 757-25-0308, and Revision 2,

dated June 12, 2023, allow accomplishment of Issue 4 of Ipeco Service Bulletin 258-25-16 for Ipeco P/N 3A258-0007-01-1 or 3A258-0008-01-1. Delta stated that accomplishing Issue 4, 5, or 6 of Ipeco Service Bulletin 258-25-15 triggers repetitive inspections of the seats but accomplishing Issue 4 or 5 of Ipeco Service Bulletin 258-25-16 terminates those repetitive inspections.

The FAA agrees with the commenter's request for the reasons provided above. Accordingly, the FAA has included the additional service information in table 1 to paragraph (m) of this AD.

Request To Emphasize Whistleblower Protections

An anonymous commenter stated the proposed AD should explicitly remind operators of the strong whistleblower protections with anti-retaliatory safeguards for mechanics, flightcrews, and inspectors who report recurring or unresolved seat movement issues.

The FAA acknowledges the commenter's concern. The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (49 U.S.C. 42121) prohibits discrimination against employees of the U.S. air carrier industry and U.S. manufacturers who report information related to air carrier safety. Employees of U.S. air carriers and U.S. aircraft/component manufacturers, their contractors, and their sub-contractors are covered under the AIR-21 Whistleblower Protection Program. More information about this program is available at <https://www.faa.gov/about/initiatives/whistleblower>. Other individuals may file a complaint or safety report using the FAA Hotline. More information about this program is available at https://www.faa.gov/about/office_org/headquarters_offices/ae/programs/services/faq_hotlines. No change to the AD is necessary in this regard.

Request To Consider Impacts on Small Businesses and Communities

An anonymous commenter requested that the FAA analyze whether additional costs or delays from the proposed AD would disproportionately affect small operators, regional airlines, or routes serving low-income or rural communities. The commenter stated that technical support or grants may be needed to avoid reducing affordable and equitable access to air service.

The FAA acknowledges the commenter's concern. The FAA recognizes that this AD imposes certain operational costs on operators, and that operators have an obligation to maintain their airplanes in airworthy condition.

However, the FAA does not provide economic mitigation to small or large operators. Under certain circumstances, an airplane manufacturer might provide warranty coverage, but the FAA does not have the authority to require manufacturers to do so. The FAA has not changed the AD in this regard.

Request To Require Reporting

An anonymous commenter requested that the FAA require operators to report anonymized data on all incidents of uncommanded seat movement, repairs performed, and root causes, with public summaries released regularly. The commenter stated that this transparency would build trust and allow independent safety and labor advocates to monitor implementation.

The FAA agrees. The holder of a type certificate, parts manufacturer approval (PMA), or technical standard order (TSO) authorization is required, under 14 CFR 21.3, to report any failure, malfunction, or defect in any product or article manufactured by it that has resulted in occurrences, as provided in § 21.3(c). These reports can be submitted to the service difficulty reporting (SDR) system at sdrs.faa.gov, which is accessible to the public. No change to the AD is necessary in this regard.

Request To Address Safety and Accessibility for Disabled Passengers

An anonymous commenter requested that the FAA revise the proposed AD to require that any new or retrofitted seat meet or exceed the American with Disabilities Act (ADA) accessibility requirements for disabled passengers and crew members.

The FAA acknowledges the commenter's concern. The requirements of this AD address uncommanded movement of the Captain's and First Officer's seats, which could lead to reduced controllability of the airplane. Therefore, this AD does not affect disabled passengers or cabin crewmembers. If a modification to a seat is needed to accommodate a disabled flightcrew member, and the modification affects compliance with this AD, an operator may request approval of an alternative method of compliance (AMOC) under the provisions of paragraph (n) of this AD. The FAA has not revised the AD in this regard.

Request To Address Compliance Time and Workforce Capacity

An anonymous commenter requested the FAA confirm that the proposed compliance time would not result in overburdening maintenance staff, forced

overtime, or flight cancellations. The commenter stated that rushed or under-resourced implementation of an AD risks maintenance errors and fatigue.

The FAA acknowledges the commenter's concern. In developing an appropriate compliance time for this AD, the FAA considered the recommendations of the manufacturer, the urgency associated with the subject unsafe condition, the availability of required parts, and the practical aspect of accomplishing the required modification within a period of time that corresponds to the normal scheduled maintenance for most affected operators. In consideration of these items, the FAA has determined that the compliance time required by this AD will ensure an acceptable level of safety. However, under the provisions of paragraph (n) of this AD, the FAA will consider requests for approval of an extension of the compliance time if sufficient data are submitted to substantiate that the new compliance time would provide an acceptable level of safety. The FAA has not changed this AD in this regard.

Request To Include Stakeholder Input

An anonymous commenter requested that the FAA require meaningful input from frontline mechanics, labor unions, flightcrew representatives, and disability rights groups before finalizing compliance plans or altering seat design standards.

The FAA acknowledges the commenter's concern. The FAA provides industry stakeholders the opportunity to participate in the rulemaking process by providing notice in the **Federal Register**. Before issuing the final rule, the FAA considers all comments received and determines whether air safety requires incorporating any requested changes or adopting the AD as proposed. No change to the AD is necessary in this regard.

Request To Address Environmental Impacts

An anonymous commenter requested that the FAA revise the proposed AD to clarify the environmental impact of seat replacement or repairs, including discarded parts and whether materials are reused or recycled. The commenter asserted that the FAA should prioritize sustainable disposal and recycling practices.

The FAA disagrees with the request. In accordance with 14 CFR 39.5, the FAA issues an AD when an unsafe condition exists on an aircraft, aircraft engine, propellers, or appliances, and the condition is likely to exist or

develop in other products of the same type design. Mandating how operators dispose of parts removed from an airplane or their spares inventory does not address the unsafe condition. Further, according to § 39.11, an AD specifies the actions that must be taken to resolve the unsafe condition. Any actions required beyond that may create an unnecessary burden on operators. The FAA has not revised the AD in this regard.

Request To Address Worker Safety

An anonymous commenter requested that the FAA revise the proposed AD to require robust reporting, training, and oversight to protect maintenance workers who inspect and repair the affected seats. The commenter stated seat maintenance can involve awkward and hazardous positions, and the FAA should ensure that airlines are required to provide safe working conditions, ergonomic equipment, and paid time for proper safety procedures.

The FAA disagrees with revising the AD. As stated previously, the FAA issues an AD to require the necessary actions to adequately address an unsafe condition on an affected product. The safety and protection of maintenance workers is outside the scope of this AD. The FAA has not revised the AD in this regard.

Request To Consider Labor Rights

An anonymous commenter asked if the FAA has a plan to monitor and enforce labor standards and fair working conditions in the manufacturing and supply chain for replacement of seat parts. The commenter stated that the proposed AD should not create pressure to outsource work to low-wage and -rights facilities.

The FAA does not plan to monitor or enforce labor standards and working conditions related to the production and supply of replacement seat parts. The enforcement of labor standards and fair working conditions is outside the scope of this AD. As stated previously, the FAA issues an AD to require the necessary actions to adequately address an unsafe condition on an affected product. The FAA has not changed the AD in this regard.

Request To Address Airline Cost Pass-Through

An anonymous commenter asked what measures the FAA will take to prevent airlines from passing on AD compliance costs directly to passengers through fare increases or fees, which disproportionately burden working-class travelers.

The FAA acknowledges the commenter's concern. As stated previously, the FAA issues an AD to require the necessary actions to adequately address an unsafe condition on an affected product. The FAA's authority to regulate air safety does not include prescribing how a private company conducts its business. The FAA has not changed the AD in this regard.

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 the foregoing changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023. This material specifies procedures for repetitive horizontal actuator identifications, repetitive checks of the HMS, a detailed inspection of the HMS, as applicable, and applicable on-condition actions including an overhaul and checks of the HMS, with the option to install a serviceable seat under certain conditions, which terminates the repetitive checks.

The FAA reviewed Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023. This material specifies procedures for a general visual inspection to determine the seat part numbers on the Captain's and First Officer's seats, and, for seats with certain part numbers, a manual override cable adjustment check of the Captain's and First Officer's seats, and applicable on-condition actions including moving the adjustment nut, tightening the lock nut, and readjusting the control lever.

This AD also requires Boeing Special Attention Service Bulletin 757–25–0308, Revision 1, dated June 7, 2018, which the Director of the Federal Register approved for incorporation by reference as of January 31, 2019 (83 FR 66612, December 27, 2018).

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.

Costs of Compliance

The FAA estimates that this AD affects 484 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Identification/check (retained actions from AD 2018–26–03).	Up to 11 work-hours × \$85 per hour = \$935 per identification/cycle.	\$4,820	\$5,755 per identification/cycle.	\$2,785,420 per identification/cycle.
Inspection (retained action from AD 2018–26–03).	Up to 1 work-hour × 85 per hour = 85 ..	0	Up to 85	41,140.
Part identification (new action)	1 work-hour × 85 per hour = 85	0	85	41,140.

Certain configurations of the Captain's and First Officer's seats may require special tooling to test the seats. Special tooling for one set of Captain's and First Officer's seats will cost \$30,000, and a certain other set will cost \$32,500. If an operator owns both combinations of seats, the special tooling will cost up to \$62,500 per operator.

We have received no definitive data that would enable us to provide the remaining cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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:

■ a. Removing Airworthiness Directive (AD) 2018–26–03, Amendment 39–19533 (83 FR 66612, December 27, 2018); and

■ b. Adding the following new AD:

2025–20–14 The Boeing Company:
Amendment 39–23167; Docket No. FAA–2025–0473; Project Identifier AD–2024–00281–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 2, 2026.

(b) Affected ADs

This AD replaces AD 2018–26–03, Amendment 39–19533 (83 FR 66612, December 27, 2018) (AD 2018–26–03).

(c) Applicability

This AD applies to all The Boeing Company Model 757–200 series airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of uncommanded movement of the Captain's and First Officer's seats. The FAA is issuing this AD to address uncommanded movement of the Captain's or First Officer's seat, which could lead to reduced controllability of the airplane.

(f) Compliance

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

(g) Identification, Checks and Inspection of Horizontal Movement System, and On-Condition Actions

For airplanes identified in Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023: Except as required by paragraphs (i) and (m) of this AD, at the applicable times specified in paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 757–25–0308, Revision 1, dated June 7, 2018, or Revision 2, dated June 12, 2023, do all applicable actions identified as "RC" (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–25–0308, Revision 1, dated June 7, 2018, or Revision 2, dated June 12, 2023. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023, may be used.

(h) Seat Identification, Cable Adjustment, and On-Condition Actions

For airplanes identified in Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023: Except as specified by paragraphs (i) and (m) of this AD, at the applicable times specified in the "Compliance" paragraph of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023, do an inspection to determine the part number of the Captain's and First Officer's seats, and all applicable on-condition actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the Captain's and First Officer's seats can be conclusively determined from that review.

(i) Exceptions to Service Bulletin Specifications for Paragraphs (g) and (h) of This AD

(1) Where the “Compliance” paragraph of Boeing Special Attention Service Bulletin 757–25–0308, Revision 1, dated June 7, 2018, refers to the original issue date of this service bulletin, this AD requires using January 31, 2019 (the effective date of AD 2018–26–03).

(2) Where the “Compliance” paragraph of Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023, refers to the original issue date of this service bulletin, this AD requires using January 31, 2019 (the effective date of AD 2018–26–03).

(3) Where the “Compliance” paragraph of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023, refers to 72 months after the original issue date of this service bulletin, this AD requires using 36 months after January 31, 2019 (the effective date of AD 2018–26–03).

(4) Where the “Compliance” paragraph of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023, refers to the Revision 2 date of this service bulletin, this AD requires using the effective date of this AD.

(j) Identification, Checks and Inspection of Horizontal Movement System, and On-Condition Actions for Additional Airplanes

For airplanes other than those identified in Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023: Except as required by paragraphs (l) and (m) of this AD, at the applicable times

specified in paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023, do all applicable actions identified as “RC” (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023.

(k) Seat Identification, Cable Adjustment, and On-Condition Actions for Additional Airplanes

For airplanes other than those identified in Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023: Except as specified by paragraphs (l) and (m) of this AD, at the applicable times specified in the “Compliance” paragraph of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023, do an inspection to determine the part number of the Captain’s and First Officer’s seats, and all applicable on-condition actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the Captain’s and First Officer’s seats can be conclusively determined from that review.

(l) Exceptions to Service Bulletin Specifications for Paragraphs (j) and (k) of This AD

(1) Where the “Compliance” paragraph of Boeing Special Attention Service Bulletin

757–25–0308, Revision 2, dated June 12, 2023, refers to the original issue date of this service bulletin, this AD requires using the effective date of this AD.

(2) Where the “Compliance” paragraph of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023, refers to 72 months after the original issue date of this service bulletin, this AD requires using 36 months after the effective date of this AD.

(3) Where the “Compliance” paragraph of Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023, refers to the Revision 2 date of this service bulletin, this AD requires using the effective date of this AD.

(m) Acceptable Conditions for Compliance

If the airplane records show that an Ipeco Captain’s or First Officer’s seat installed on an airplane meets the conditions in any of the three rows for Boeing Special Attention Service Bulletin 757–25–0308 in table 1 to paragraph (m) of this AD, then the actions in paragraphs (g) and (j), as applicable, of this AD are not required for that seat. If the airplane records show that an Ipeco Captain’s or First Officer’s seat installed on an airplane meets the conditions in any of the three rows for Boeing Special Attention Service Bulletin 757–25–0309 in table 1 to paragraph (m) of this AD, then the actions specified in paragraphs (h) and (k), as applicable, of this AD are not required for that seat.

TABLE 1 TO PARAGRAPH (m)—ALTERNATIVE ACCEPTABLE SEATS

Actions done in accordance with Boeing Special Attention Service Bulletin—	Actions done in accordance with Ipeco Service Bulletin—	Having Ipeco part number (P/N)	And additional required conditions—
757–25–0308, Revision 1, dated June 7, 2018, or Revision 2, dated June 12, 2023.	None	3A258–0007–01–2, 3A258–0007–01–1Z, 3A258–0008–01–2, or 3A258–0008–01–1Z.	No additional conditions required.
757–25–0308, Revision 1, dated June 7, 2018, or Revision 2, dated June 12, 2023.	258–25–15, Issue 4, dated February 16, 2018; Issue 5, dated April 29, 2020; or Issue 6, dated November 1, 2021.	3A258–0007–01–1 or 3A258–0008–01–1.	Has a horizontal actuator with Artus part number AD8650503 at “Amendment C” or later.
757–25–0308, Revision 1, dated June 7, 2018, or Revision 2, dated June 12, 2023.	258–25–16, Issue 4, dated September 11, 2017; or Issue 5, dated April 29, 2020.	3A258–0007–01–1 or 3A258–0008–01–1.	Has a horizontal actuator with Artus part number AD8650503 at “Amendment C” or later.
757–25–0309, Revision 1, dated July 2, 2018, or Revision 2, dated June 12, 2023.	None	3A258–0007–01–2 or 3A258–0008–01–2.	No additional conditions required.
757–25–0309, Revision 1, dated July 2, 2018, or Revision 2, dated June 12, 2023.	258–25–08, Issue 4, dated April 25, 2014; Issue 5, dated March 4, 2020; or Issue 6, dated January 28, 2021.	3A258–0007–01–1, 3A258–0007–01–1Z, 3A258–0008–01–1, or 3A258–0008–01–1Z.	The manual override cable maintenance has been completed on the seat in accordance with Ipeco Component Maintenance Manual 25–11–26, Revision 16, dated September 12, 2013, or subsequent revisions up to and including Revision 40, dated December 4, 2023.
757–25–0309, Revision 1, dated July 2, 2018, or Revision 2, dated June 12, 2023.	210–25–04, Issue 2, dated March 28, 2014; or Issue 3, dated March 3, 2020.	3A090–0077–01–1 or 3A090–0078–01–1.	The manual override cable maintenance has been completed on the seat in accordance with Ipeco Component Maintenance Manual 25–10–78, Revision 20, dated September 12, 2013, or subsequent revisions up to and including Revision 29, dated October 13, 2023.

(n) 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 (o) of this AD. Information may be emailed to: AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) 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.

(3) AMOCs approved for AD 2018–26–03 are approved as AMOCs for the corresponding provisions of this AD.

(4) For material that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (n)(4)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled “RC Exempt,” then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(o) Related Information

For more information about this AD, contact Julie Linn, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3584; email: Julie.Linn@faa.gov.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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.

(3) The following material was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) Boeing Special Attention Service Bulletin 757–25–0308, Revision 2, dated June 12, 2023.

(ii) Boeing Special Attention Service Bulletin 757–25–0309, Revision 2, dated June 12, 2023.

(4) The following material was approved for IBR on January 31, 2019 (83 FR 66612, December 27, 2018).

(i) Boeing Special Attention Service Bulletin 757–25–0308, Revision 1, dated June 7, 2018.

(ii) [Reserved]

(5) For Boeing 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.

(6) 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.

(7) 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 29, 2025.

Lona C. Saccomando,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–21474 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1895; Project Identifier MCAL–2023–01240–T; Amendment 39–23168; AD 2025–20–15]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–08–08, which applied to certain Airbus SAS Model A318 series airplanes; 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, and –232 airplanes. AD 2022–08–08 required repetitive special detailed inspections of certain double joggle areas on the fuselage and applicable on-condition actions. Since the FAA issued AD 2022–08–08, it was determined that additional airplane models are subject to the unsafe condition and additional requirements are necessary for airplanes repaired after accomplishment of certain airworthiness limitations item (ALI) tasks. This AD continues to require the actions in AD 2022–08–08. This AD also adds airplane models to the applicability and additional requirements for certain airplanes. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2026. The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2024–1895; 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, the mandatory continuing airworthiness information (MCAI), 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.

Material Incorporated by Reference:

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

- 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–2024–1895.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3667; email: Timothy.P.Dowling@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2022–08–08, Amendment 39–22011 (87 FR 23755, April 21, 2022) (AD 2022–08–08). AD 2022–08–08 applied to certain Airbus SAS Model A318 series airplanes; 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, and –232 airplanes. AD 2022–08–08 required repetitive special detailed inspections of certain areas and applicable on-condition actions. The FAA issued AD 2022–08–08 to address cracks in the double joggle areas at frame (FR) 16 and FR20, right-hand and left-hand sides, which, if not detected and corrected, could reduce the structural integrity of the fuselage.

The NPRM was published in the **Federal Register** on July 24, 2024 (89 FR 59857). The NPRM was prompted by AD 2023–0212, dated December 6, 2023

(EASA AD 2023–0212), issued by EASA, which is the Technical Agent for the Member States of the European Union. EASA AD 2023–0212 states that the unsafe condition may also exist on Airbus SAS A318/A320/A321 “NEO” airplanes (*i.e.*, Airbus SAS Model A318–151N, –153N, and –171N; A320–251N, –252N, –253N, –271N, –272N, and –273N; and A321–251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes), so these airplanes are added to the applicability. In addition, Airbus has developed additional, new structural repair manual (SRM) tasks that are considered additional alternative methods to the Airbus repair designs originally required by EASA AD 2021–0227, dated October 11, 2021, for the airplanes affected by that AD.

In the NPRM, the FAA proposed to continue to require the actions in AD 2022–08–08 and add NEO airplane models to the applicability, as specified in EASA AD 2023–0212.

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 to supersede AD 2022–08–08. The SNPRM was published in the **Federal Register** on February 18, 2025 (90 FR 9695). The SNPRM was prompted EASA AD 2024–0217, dated November 18, 2024 (EASA AD 2024–0217) (also referred to as “the MCAI”), which superseded EASA AD 2023–0212. Since EASA AD 2023–0212 was issued, it was determined that AD-mandated repetitive inspections were incorrectly terminated for all the Airbus repair instructions; only those in which the termination of the AD-mandated inspections was explicitly written in the Airbus-approved instructions should have been terminated. Therefore, additional requirements are necessary for airplanes that have been repaired after accomplishment of ALI tasks 531153–02 or 531155–02.

In the SNPRM, the FAA revised the NPRM by adding additional requirements for airplanes that have been repaired after accomplishment of ALI task 531153–02 or 531155–02. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2024–1895.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from an individual who supported the SNPRM without change.

The FAA received additional comments from Delta Air Lines (Delta)

and an individual. The following presents the comment received on the SNPRM and the FAA’s response.

Request To Require Inspections Be Completed by the FAA

An individual requested that the FAA be required to inspect all affected airplanes to determine if there is significant damage. The individual also requested that any safety requirements of the proposed AD be repaired before further flight.

The FAA agrees to clarify. The actions required by this AD are the responsibility of operators. FAA regulations (14 CFR 43.3) stipulate who can perform maintenance on or alter an airplane on the U.S. registry, including inspections required by an AD. AD actions must be performed by people holding certain certificates or having specialized training that provides them the knowledge necessary to properly inspect and repair airplanes. In addition, this AD requires operators to address any cracks that are detected before further flight. The FAA has not revised the AD in this regard.

Request To Terminate Certain SRM Inspections

Delta requested that the FAA add an exception to paragraph (h) of the proposed AD to specify that the repetitive inspections in paragraph (1) of EASA AD 2024–0217 supersede the repetitive inspections in SRM task 53–11–12–205–008 or 53–11–12–205–007, as applicable. Delta stated that, if cracking is found, two of the service bulletins referenced in the Corrective Action(s) paragraph of EASA AD 2024–0217 specify to repair using SRM task 53–11–12–300–012 or 53–11–12–300–013, which in turn specify doing repetitive inspections per SRM task 53–11–12–205–008 or SRM task 53–11–12–205–007, respectively. Delta also stated that SRM tasks 53–11–12–205–008 and SRM task 53–11–12–205–007 do not specify that these repetitive inspections supersede, replace, or terminate the repetitive inspections in paragraph (1) of EASA AD 2024–0217. Delta asserted this results in duplicative repetitive inspections of the same area at different compliance times since accomplishing the corrective action also does not terminate the repetitive inspections in paragraph (1) of EASA AD 2024–0217.

The FAA agrees that the AD is not intended to require duplicative repetitive inspections. However, the FAA has determined that an exception is not necessary. This AD only requires the repetitive inspections to be done in accordance with paragraph (1) of the EASA AD except as specified in

paragraph (7) of EASA AD 2024–0217. The provision in paragraph (7) of EASA 2024–0217 specifies “unless specified otherwise in the instructions provided by Airbus”, which applies to the statement in the material referenced in paragraph (1) of EASA AD 2024–0217 that states to repeat the inspection for the non-repaired hole(s). Therefore, paragraph (1) of EASA AD 2024–0217 does not require repetitive inspections of repaired holes at those locations. However, the repetitive post-repair inspections referenced in SRM tasks 53–11–12–205–008 and 53–11–12–205–007 may be required for compliance with paragraph (2) of EASA AD 2024–0217. The FAA has not revised the AD in this regard.

Additional Changes Made to This AD

In the SNPRM, the FAA stated that accomplishing the required actions would terminate ALI tasks 531153–02–1, 531153–02–2, 531155–02–1, and 531155–02–2, as required by paragraph (o) of AD 2023–13–10, Amendment 39–22495 (88 FR 50005, August 1, 2023) (AD 2023–13–10). AD 2023–13–10 has since been superseded by AD 2025–03–06, Amendment 39–22954 (90 FR 9595, February 14, 2025) (AD 2025–03–06). The service information referenced in AD 2025–03–06 revises ALI tasks 531153–02–1 and 531155–02–1 and deletes ALI tasks 531153–02–2 and 531155–02–2. The FAA has therefore revised paragraph (b)(2) of this AD to specify that it affects AD 2025–03–06 and revised paragraph (j) of this AD to specify that accomplishing the actions required by this AD terminates ALI tasks 531153–02–1 and 531155–02–1 as required by paragraph (n) of AD 2025–03–06.

Additionally, in the SNPRM the FAA inadvertently omitted an exception to require using the effective date of this AD in lieu of the effective date of EASA AD 2024–0217. The FAA has added paragraph (h)(4) of this AD to include this exception.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. 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 this product. Except for

minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the SNPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0217, which specifies procedures for repetitive special detailed inspections for cracking of double joggle areas at FR16 and FR20, right-hand and left-hand sides, applicable on-condition actions (repair), and an optional

modification of the double joggle area that terminates the repetitive inspections. The modification includes a rotating probe inspection of certain fastener holes for cracks, a check of the fastener holes for a minimum diameter, and applicable on-condition actions. EASA AD 2024–0217 also specifies that new SRM tasks have been developed that are acceptable for compliance with the corrective actions required by AD 2022–08–08 for airplanes affected by that AD. EASA AD 2024–0217 specifies additional requirements for airplanes

that have been repaired after accomplishment of ALI task 531153–02 or 531155–02.

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.

Costs of Compliance

The FAA estimates that this AD affects 1,755 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 55 work-hours × \$85 per hour = Up to \$4,675	\$0	Up to \$4,675	Up to \$8,204,625.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
60 work-hours × \$85 per hour = \$5,100	\$1,624	\$6,724

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

Authority for This Rulemaking

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

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

Regulatory Findings

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:
■ a. Removing Airworthiness Directive (AD) 2022–08–08, Amendment 39–22011 (87 FR 23755, April 21, 2022); and
■ b. Adding the following new AD:

2025–20–15 Airbus SAS: Amendment 39–23168; Docket No. FAA–2024–1895; Project Identifier MCAI–2023–01240–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 2, 2026.

(b) Affected ADs

(1) This AD replaces AD 2022–08–08, Amendment 39–22011 (87 FR 23755, April 21, 2022) (AD 2022–08–08).
(2) This AD affects AD 2025–03–06, Amendment 39–22954 (90 FR 9595, February 14, 2025) (AD 2025–03–06).

(c) Applicability

This AD applies to Airbus SAS Model airplanes specified in paragraphs (c)(1) through (4) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2024–0217, dated November 18, 2024 (EASA AD 2024–0217).

- (1) Model A318–111, –112, –121, and –122 airplanes.
- (2) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes.
- (3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.
- (4) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports that, during inspections accomplished as specified in certain airworthiness limitation items (ALIs), cracks were detected in the double joggle areas at frame (FR) 16 and FR20 in the nose forward fuselage. The unsafe condition, if not addressed, could result in reduced structural integrity of the fuselage.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0217.

(h) Exceptions to EASA AD 2024–0217

(1) Replace paragraph (3) of EASA AD 2024–0217 with “For an airplane that has been repaired before the effective date of this AD in an affected area using Airbus-approved instructions unrelated to (not a result of a finding during an ALI inspection or the inspection SB) ALI task 531153–02–1, 531153–02–2, 531155–02–1, 531155–02–2, 531153–03–1, 531155–03–1 or the inspection SB, as applicable: Before exceeding the thresholds as specified in Table 1 (for CEO airplanes) or Table 2 (for NEO airplanes) of this AD, as applicable, contact the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA)s for approved instructions and accomplish those instructions accordingly. If approved by the DOA, the approval must include the DOA-authorized signature.”

(2) Where paragraph (4) of EASA AD 2024–0217 specifies to “contact Airbus for approved repair instructions and, within the compliance time specified therein, accomplish those instructions accordingly” if any cracks are detected, for this AD if any cracking is detected, the cracking must be repaired before further flight using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) This AD does not adopt the “Remarks” section of EASA AD 2024–0217.

(4) Where EASA AD 2024–0217 refers to its effective date, this AD requires using the effective date of this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2024–0217 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Terminating Action for Certain Requirements in AD 2025–03–06

Accomplishing the actions required by this AD terminates ALI tasks 531153–02–1, and 531155–02–1 as required by paragraph (n) of AD 2025–03–06 only for the airplanes identified in paragraph (c) of this AD.

(k) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: 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 Continued Operational Safety Branch, mail it to the address identified in paragraph (l) of this AD. Information may be emailed to: AMOC@faa.gov.

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

(ii) AMOCs approved previously for AD 2022–08–08 are approved as AMOCs for the corresponding provisions of EASA AD 2024–0217 that are required by paragraph (g) of this AD.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

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

(l) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3667; email: Timothy.P.Dowling@faa.gov.

(m) 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 this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0217, dated November 18, 2024.

(ii) [Reserved].

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADS@easa.europa.eu. You

may find this EASA AD on the EASA website at ad.easa.europa.eu.

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

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

Issued on October 3, 2025.

Lona C. Saccomando,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2025–21475 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 700**

[Docket ID: OSM–2025–0024; S1D1S SS08011000 SX064A000 256S180110; S2D2S SS08011000 SX064A000 25XS501520]

RIN 1029–AD04

Applicability of Federal Regulations Implementing the Surface Mining Control and Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule revises the Federal regulations to rescind obsolete regulations related to the applicability of the Federal regulations implementing the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act).

DATES: Effective January 27, 2026, the suspension at 30 CFR 700.11(b) is lifted without further action, unless significant adverse comments are received by December 29, 2025. If significant adverse comments are received, OSMRE will publish a timely withdrawal or issue a new final rule that responds to significant adverse comments.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number OSM–2025–0024. Follow the instructions for submitting comments.

• *By hard copy:* Submit by U.S. mail to Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Attn: James Tyree, 1849 C Street NW, Mail Stop 4557, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

James Tyree, Chief, Division of Regulatory Support, (202) 208-4479, jtyree@osmre.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: As originally enacted, SMCRA exempted from the requirements of the Act “the extraction of coal for commercial purposes where the surface mining operation affects two acres or less.” 30 U.S.C. 1278(2) (1977). To implement this provision, in 1979, OSMRE promulgated regulations at 30 CFR 700.11(b) to reflect that operators of surface coal mining operations affecting two acres or less were not required to comply with the permitting, land reclamation, or environmental performance requirements imposed on larger operations by the SMCRA implementing regulations. 44 FR 15311 (Mar. 13, 1979). On May 7, 1987, Public Law 100-34, 101 Stat. 300 (1987), was signed in to law, amending SMCRA by repealing the exemption for coal extraction for commercial sites affecting two acres or less. The effective date of the law was June 6, 1987, and the grace period that Congress built into the law for operations to finish mining or come into compliance with SMCRA requirements expired 6 months after the enactment, meaning that since November 8, 1987, the requirements of SMCRA apply to all surface coal mining operations regardless of size, unless exempted under some other provision of SMCRA.

On June 4, 1987, OSMRE suspended § 700.11(b) but did not remove the text from the **Federal Register**, stating its intent to pursue a separate rulemaking at a later time to revise the suspended rules, consistent with the new law (52 FR 21228). However, OSMRE never pursued a separate rulemaking, and section 700.11(b) has remained a part of the Federal regulations, inoperative and confusing, for nearly 40 years. Section 700.11(b) is not authorized under SMCRA, as amended; was rightfully

suspended nearly 40 years ago; and the obsolete text should be removed from the Code of Federal Regulations to make the regulations that implement SMCRA consistent with SMCRA and less confusing.

The Department has determined that this reason, independently and alone, justifies rescission of 30 CFR 700.11(b). The Department has no interest in maintaining rules that are obsolete.

The Department is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA, 5 U.S.C. 551-559) generally requires agencies to engage in notice and comment rulemaking, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* 553(b)(B). The Department has determined that notice and comment are unnecessary because this rule is noncontroversial; of a minor, technical nature; involves little agency discretion; and is unlikely to receive any significant adverse comments. Significant adverse comments are those that oppose the rescission of the regulations and raise, alone or in combination, (1) reasons why the rescission of the regulations is inappropriate, including challenges to the rescission’s underlying premise, or (2) serious unintended consequences of the rescission. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

Procedural Determinations

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule does not result in a taking of private property or otherwise have regulatory takings implications under Executive Order 12630. The rule rescinds obsolete regulatory provisions; therefore, the rule will not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has

determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the Nation’s regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department developed this rule in a manner consistent with these requirements.

Executive Order 12988—Civil Justice Reform

This direct final rule complies with the requirements of Executive Order 12988. Among other things, this rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation;
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria of section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This 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. A federalism summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department evaluated this direct final rule under Executive Order 13175 and the Department’s consultation policies

and determined that it has no substantial direct effects on federally recognized Indian Tribes and that consultation under the Department's Tribal consultation policies is not required. The rule merely revises the Federal regulations to remove obsolete regulatory language.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not a significant energy action as defined in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

National Environmental Policy Act

This direct final rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because this rule is covered by a categorical exclusion applicable to regulatory functions “that are of an administrative, financial, legal, technical, or procedural nature.” 43 CFR 46.210(i). In addition, the Department has determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act

This rule does not impose any new information collection burden under the Paperwork Reduction Act. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 1029-0094. This rule does not impose an information collection burden because the Department is not making any changes to the information collection requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601–612) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). As the Department is not required to publish a notice of proposed rulemaking for this direct final rule, the RFA does not apply.

Congressional Review Act

This rule is not a major rule under the Congressional Review Act, 5 U.S.C. 804(2). Specifically, the direct final rule: (a) will not have an annual effect on the economy of \$100 million or more; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments, or the private sector. The rule merely revises the Federal regulations to remove obsolete language that is no longer used. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 700

Administrative practice and procedure, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Leslie Shockley Beyer,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Department of the Interior amends 30 CFR part 700 as follows:

PART 700—GENERAL

■ 1. The authority citation for part 700 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Amend § 700.11 by:

■ a. Revising paragraph (a);

■ b. Lifting the suspension and removing paragraph (b); and

■ c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c).

The revision reads as follows:

§ 700.11 Applicability.

(a) This chapter applies to all coal exploration and surface coal mining and reclamation operations except:

* * * * *

[FR Doc. 2025–21449 Filed 11–26–25; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 816

[Docket ID: OSM–2025–0025 S1D1S
SS08011000 SX064A000 256S180110;
S2D2S SS08011000 SX064A000
25XS501520]

RIN 1029–AD03

Backfilling and Grading

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule revises the Federal regulations to rescind an obsolete regulation that was suspended by the Secretary of the Interior in 1992 and that has been inoperative for 33 years. The regulations prescribed time and distance performance standards for the completion of rough backfilling and grading for surface mining operations.

DATES: The amendments in this direct final rule lifting the suspension of 30 CFR 816.101 and removing the section are effective January 27, 2026, unless significant adverse comments are received by December 29, 2025. If significant adverse comments are received, OSMRE will publish a timely withdrawal or issue a new final rule that responds to significant adverse comments.

ADDRESSES: You may submit comments by one of the following methods:

- **Electronically:** Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number OSM–2025–0025. Follow the instructions for submitting comments.

- **By hard copy:** Submit by U.S. mail to Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Attn: James Tyree, 1849 C Street NW, Mail Stop 4557, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

James Tyree, Chief, Division of Regulatory Support, (202) 208–4479, jtyree@osmre.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: Section 515(b)(16) of SMCRA, 30 U.S.C. 1265(b)(16), provides for general performance standards to require surface coal mining and reclamation operations to “insure that all reclamation efforts proceed in an environmentally sound manner and as contemporaneously as practicable with the surface coal mining operations.” OSMRE’s initial permanent program regulations, promulgated on March 13, 1979, included a section 816.101, which provided time and distance schedules as general requirements for rough backfilling and grading (44 FR 14902, at 15411).

In a 1983 rulemaking, the Secretary made several changes to the regulations governing contemporaneous reclamation, including removing section 816.101, concluding that “‘contemporaneous reclamation’ is a relative term which must be interpreted by each State on the basis of the mining conditions in its territory.” 48 FR 23356 (May 24, 1983). These regulatory changes were challenged, *In re Permanent Surface Mining Regulation*, 21 ERC 1724, 1744–1746 (D.D.C. October 1, 1984), and the District Court for the District of Columbia remanded related regulations but not section 816.101. OSMRE appealed the district court ruling. On appeal, the D.C. Circuit held that SMCRA does not require specific regulations related to contemporary reclamation performance standards but cautioned that if there is no need to “flesh out” the statute, the agency must “flesh out” its explanation for why additional regulation is not necessary. *Nat’l Wildlife Fed’n v. Hodel*, 839 F.2d 694, 734–736 (1988).

Nonetheless, in 1991, OSMRE promulgated new time and distance performance standards for the completion of rough backfilling and grading for surface mining operations that still appear at 816.101. 56 FR 65612 (Dec. 17, 1991). Unlike prior versions and the text of the proposed rule, the 1991 rule did not contain flexibility for States to develop alternative State-specific schedules. These regulations were immediately challenged by the National Coal Association and the American Mining Congress. *Nat’l Coal Ass’n and Am. Mining Congress v. DOI*, Civ. No. 92–0408–CRR (D.D.C.). On April 16, 1992, the district court approved a joint stipulation of dismissal in which the Secretary agreed to suspend 30 CFR 816.101 and reconsider the issues raised in the rulemaking. Over 30 years ago, in 1992, the Secretary suspended, but did not remove from the Code of Federal Regulations, section 816.101. 57 FR 33874 (Jul. 31, 1992).

OSMRE now removes this unnecessary and unlawful regulatory provision from the Federal regulations.

The Department has determined that this reason, independently and alone, justifies rescission of 30 CFR 816.101. The Department has no interest in maintaining rules that are obsolete.

The Department is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA, 5 U.S.C. 551–559) generally requires agencies to engage in notice and comment rulemaking, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* § 553(b)(B). The Department has determined that notice and comment are unnecessary because this rule is noncontroversial; of a minor, technical nature; involves little agency discretion; and is unlikely to receive any significant adverse comments. Significant adverse comments are those that oppose the rescission of the regulations and raise, alone or in combination, (1) reasons why the rescission of the regulations is inappropriate, including challenges to the rescission’s underlying premise, or (2) serious unintended consequences of the rescission. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

Procedural Determinations

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule does not result in a taking of private property or otherwise have regulatory takings implications under Executive Order 12630. The rule rescinds obsolete regulatory provisions; therefore, the rule will not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the Nation’s regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department developed this rule in a manner consistent with these requirements.

Executive Order 12988—Civil Justice Reform

This direct final rule complies with the requirements of Executive Order 12988. Among other things, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation;

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria of section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This 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. A federalism summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department evaluated this direct final rule under Executive Order 13175 and the Department’s consultation policies and determined that it has no substantial direct effects on federally

recognized Indian tribes and that consultation under the Department's Tribal consultation policies is not required. The rule merely revises the Federal regulations to remove obsolete regulatory language.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not a significant energy action as defined in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

National Environmental Policy Act

This direct final rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because this rule is covered by a categorical exclusion applicable to regulatory functions “that are of an administrative, financial, legal, technical, or procedural nature.” 43 CFR 46.210(i). In addition, the Department has determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act

This rule does not impose any new information collection burden under the Paperwork Reduction Act. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 1029–0094. This rule does not impose an information collection burden because the Department is not making any changes to the information collection requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601–612) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). As the Department is not required to publish a notice of proposed rulemaking for this direct final rule, the RFA does not apply.

Congressional Review Act

This rule is not a major rule under the Congressional Review Act, 5 U.S.C. 804(2). Specifically, the direct final rule: (a) will not have an annual effect on the economy of \$100 million or more; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments, or the private sector. The rule merely revises the Federal regulations to remove obsolete language that is no longer used. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 816

Environmental protection, Reporting and recordkeeping requirements, Surface mining.

Leslie Shockley Beyer,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Department of the Interior amends 30 CFR part 816 as follows:

PART 816—PERMANENT PROGRAM PERFORMANCE STANDARDS—SURFACE MINING ACTIVITIES

■ 1. The authority citation for part 816 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.* and sec 115 of Pub. L. 98–146.

§ 816.101 [Removed and reserved]

■ 2. Lift the suspension of § 816.101 and remove and reserve the section.

[FR Doc. 2025–21440 Filed 11–26–25; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 816 and 817

[Docket No. OSM–2025–0010; S1D1S SS08011000 SX064A000 256S180110; S2D2S SS08011000 SX064A000 25XS01520]

RIN 1029–AC92

Rescission of Portions of Permanent Program Performance Standards Related to Siltation Structures

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.
ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule revises the Federal regulations to remove paragraphs that required that all surface drainage from the disturbed area pass through a siltation structure before leaving the permit area. These paragraphs were struck down on judicial review because the court found that the Office of Surface Mining Reclamation and Enforcement (OSMRE) had not articulated a sufficient basis for the rule under the Administrative Procedure Act and that OSMRE had not sufficiently demonstrated that siltation structures were the best technology currently available.

DATES: The final rule is effective January 27, 2026, unless significant adverse comments are received by December 29, 2025. If significant adverse comments are received, notice will be published in the **Federal Register** before the effective date either withdrawing the rule or issuing a new final rule which responds to significant adverse comments.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number OSM–2025–0010. Follow the instructions for submitting comments.
- *By hard copy:* Submit by U.S. mail to Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Attn: James Tyree, 1849 C Street NW, Mail Stop 4557, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: James Tyree, Division of Regulatory Support, (202) 208–4479, jtyree@osmre.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:

Paragraphs (b)(1) from both 30 CFR 816.46 and 30 CFR 817.46 require that “additional contributions of suspended solids sediment to streamflow or runoff outside the permit area shall be prevented to the extent possible using best technology currently available.” Paragraphs (b)(2) of sections 816.46 and 817.46 required that all surface drainage from the disturbed area pass through a siltation structure before leaving the permit area. Forty years ago, paragraphs (b)(2) of sections 816.46 and 817.46 were struck down on judicial review because the court found that OSMRE had not articulated a sufficient basis for the rule under the Administrative Procedure Act and that OSMRE had not sufficiently demonstrated that siltation structures were the best technology currently available in every case. *See In re Permanent Surface Mining Regulation Litigation*, 620 F. Supp. 1519, 1566–1568 (D.D.C. 1985).

In response to the court’s holding, OSMRE suspended paragraphs (b)(2) from both 30 CFR 816.46 and 30 CFR 817.46 on November 20, 1986, but did not remove them from the Code of Federal Regulations. 51 FR 41961 (Nov. 20, 1986). To avoid confusion that might result from the continuing publication of those rules in the Federal regulations, over a decade later, OSMRE attempted to remove paragraphs (b)(2) from sections 816.46 and 817.46 and redesignate the remaining paragraphs of those sections accordingly. 73 FR 75814, 75854 (Dec. 12, 2008). At that time, however, OSMRE omitted the words “lift the suspension” prior to directing the removal of the paragraphs, which had the effect of rendering the removal of those paragraphs inoperable. On September 29, 2010, OSMRE published technical amendments, that among other things lifted the suspension and removed the paragraphs. 75 FR 60272. However, when the Stream Buffer Rule was vacated, a final rule was published that erroneously reinstated the suspended provisions from the 2008 rule albeit with a sentence noting the suspension instead of an actual suspension. *See, e.g.*, 79 FR 76227 (Dec. 22, 2014). OSMRE attempted to remove the provisions again as part of the Stream Protection Rule. 81 FR 93392 (Dec. 20, 2016). However, that rule was later disapproved by Congress and the

prior language was reinstated. 82 FR 54979 (Nov. 17, 2017).

Upon reviewing these regulations, the 1985 court decision, and the various **Federal Register** notices attempting to rescind these regulations, OSMRE has determined that they should finally be rescinded because they were struck down upon judicial review and paragraph (b)(1) in sections 816.46 and 817.46 ensure that the best technology currently available, which may include siltation structures, is used to prevent, to the extent possible, additional contributions of suspended solids sediment to streamflow or runoff outside the permit area. Additionally, because the suspension was lifted in 2010, no further action is necessary to lift the suspension at this time. This reason, independently and alone, justifies rescission of paragraphs (b)(2) from both 30 CFR 816.46 and 30 CFR 817.46. OSMRE has no interest in maintaining regulations that have been struck down by court order.

The Department is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA, 5 U.S.C. 551–559) generally requires agencies to engage in notice and comment rulemaking, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* § 553(b)(B). The Department has determined that notice and comment are unnecessary because this rule is noncontroversial; of a minor, technical nature; involves no agency discretion; and is unlikely to receive any significant adverse comments. Significant adverse comments are those that oppose the rescission of the rule and raise, alone or in combination, (1) reasons why the rescission of the rule is inappropriate, including challenges to the rescission’s underlying premise, or (2) serious unintended consequences of the rescission. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

Procedural Determinations

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule does not result in a taking of private property or otherwise have regulatory takings implications under Executive Order 12630. The rule rescinds a regulatory provision suspended by a court since 1985;

therefore, the rule will not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the Nation’s regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department developed this rule in a manner consistent with these requirements.

Executive Order 12988—Civil Justice Reform

This direct final rule complies with the requirements of Executive Order 12988. Among other things, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation;

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria of section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This 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. A federalism

summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department evaluated this direct final rule under Executive Order 13175 and the Department's consultation policies and determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's Tribal consultation policies is not required. The rule merely revises the Federal regulations to remove language made obsolete by a 1985 court ruling.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not a significant energy action as defined in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

National Environmental Policy Act

This direct final rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because this rule is covered by a categorical exclusion applicable to regulatory functions “that are of an administrative, financial, legal, technical, or procedural nature.” 43 CFR 46.210(i). In addition, the Department has determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act

This rule does not impose any new information collection burden under the Paperwork Reduction Act. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 1029–0047. This rule does not impose an information collection burden because the Department is not making any changes to the information collection requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601–612) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). As the Department is not required to publish a notice of proposed rulemaking for this direct final rule, the RFA does not apply.

Congressional Review Act

This rule is not a major rule under the Congressional Review Act (5 U.S.C. 804(2)). Specifically, the direct final rule: (a) will not have an annual effect on the economy of \$100 million or more; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments, or the private sector. The rule merely revises the Federal regulations to remove an obsolete provision that is no longer used. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects

30 CFR 816

Environmental protection, Reporting and recordkeeping requirements, Surface mining.

30 CFR 817

Environmental protection, Reporting and recordkeeping requirements, Underground mining.

Leslie Shockley Beyer,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Department of the Interior

amends 30 CFR parts 816 and 817 as follows:

PART 816—PERMANENT PROGRAM PERFORMANCE STANDARDS—SURFACE MINING ACTIVITIES

■ 1. The authority citation for part 816 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*; and sec 115 of Pub. L. 98–146.

§ 816.46 [Amended]

■ 2. Amend § 816.46, by removing paragraph (b)(2), and redesignating paragraphs (b)(3) through (6) as paragraphs (b)(2) through (5).

PART 817—PERMANENT PROGRAM PERFORMANCE STANDARDS—UNDERGROUND MINING ACTIVITIES

■ 3. The authority citation for part 817 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

§ 817.46 [Amended]

■ 4. Amend 817.46, by removing paragraph (b)(2), and redesignating paragraphs (b)(3) through (7) as paragraphs (b)(2) through (6).

[FR Doc. 2025–21441 Filed 11–26–25; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 817

[Docket No. OSM–2025–0009; S1D1S SS08011000 SX064A000 256S180110; S2D2S SS08011000 SX064A000 25XS501520]

RIN 1029–AC91

Rescission of Portions of Permanent Program Performance Standards Regulating Subsidence Controls for Underground Mines

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule lifts the suspension and revises the Federal regulations to remove paragraphs related to establishing a rebuttable presumption of causation for damage to any non-commercial building or occupied residential dwelling or structure related thereto that occurs as a result of earth movement within an area determined by projecting a specified angle of draw from the outermost boundary of any underground

mine workings to the surface of the land. These paragraphs were struck down on judicial review because the court found that the Office of Surface Mining Reclamation and Enforcement (OSMRE) failed to provide adequate support to justify its presumption that damage was the result of mining within the angle of draw.

DATES: The amendments in this direct final rule lifting the suspension at 30 CFR 817.(c)(4)(i) through (iv) and amending the section are effective January 27, 2026, without further action, unless significant adverse comments are received by December 29, 2025. If significant adverse comments are received, OSMRE will publish a timely withdrawal or issue a new final rule that responds to significant adverse comments.

ADDRESSES: You may submit comments by one of the following methods:

- **Electronically:** Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number [OSM–2025–0009]. Follow the instructions for submitting comments.

- **By hard copy:** Submit by U.S. mail to Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Attn: James Tyree, 1849 C Street NW, Mail Stop 4557, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: James Tyree, Division of Regulatory Support, (202) 208–4479, jtyree@osmre.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:

Paragraphs (c)(4)(i) through (c)(4)(iv) of 30 CFR 817.121 provided that if damage to any non-commercial building or occupied residential dwelling or structures related thereto occurs as a result of earth movement within an area determined by projecting a specified angle of draw from the outermost boundary of any underground mine workings to the surface of the land, a rebuttable presumption would exist that the permittee caused the damage. The presumption typically would have applied to a 30-degree angle of draw. Once the presumption was triggered, the burden of going forward shifted to the mine operator to offer evidence that the

damage was attributable to another cause.

Over 25 years ago, these provisions were struck down on judicial review because the court found that OSMRE failed to provide adequate support to justify its presumption that damage was the result of mining within the angle of draw. *Nat'l Mining Ass'n v. Babbitt*, 172 F.3d 906, 912 (1999). In response to the court's holding, OSMRE suspended these provisions on December 22, 1999, but did not remove the language from the Code of Federal Regulations. 64 FR 71652, 71653 (Dec. 22, 1999). OSMRE attempted to lift the suspension and remove these provisions as part of the Stream Protection Rule in 2016 (81 FR 93418 (Dec. 20, 2020)). However, all proposed changes to OSMRE's regulations under the Stream Protection Rule were disapproved by Joint Resolution under the Congressional Review Act. Consequently, these removed provisions were reinstated. 82 FR 54924 (Nov. 17, 2017). Although we recognize that the Congressional Review Act at 5 U.S.C. 801(b)(2) prevents OSMRE from reissuing the Stream Protection Rule in substantially the same form, we find that lifting the suspension and removing these provisions regarding a rebuttable presumption of causation is not substantially the same as the Stream Protection Rule because of the housekeeping and ministerial nature of removing an inoperative regulation.

Upon reviewing these regulations, OSMRE has determined that the suspension should be lifted and paragraphs (c)(4)(i) through (c)(4)(iv) of 30 CFR 817.121 should be rescinded because they were vacated by court order in 1999, and it is confusing to allow these inoperative provisions to remain in OSMRE's regulations. This reason, independently and alone, justifies rescission of paragraphs (c)(4)(i) through (c)(4)(iv) of 30 CFR 817.121. OSMRE has no interest in maintaining regulations that have been vacated by court order.

The Department is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA, 5 U.S.C. 551–559) generally requires agencies to engage in notice and comment rulemaking, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* § 553(b)(B). The Department has determined that notice and comment are unnecessary because this rule is noncontroversial; of a minor, technical nature; involves little agency discretion; and is unlikely to receive

any significant adverse comments. Significant adverse comments are those that oppose the rescission of the rule and raise, alone or in combination, (1) reasons why the rescission of the rule is inappropriate, including challenges to the rescission's underlying premise, or (2) serious unintended consequences of the rescission. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

Procedural Determinations

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule does not result in a taking of private property or otherwise have regulatory takings implications under Executive Order 12630. The rule rescinds a regulatory provision vacated by a court in 1999; therefore, the rule will not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the Nation's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department developed this rule in a manner consistent with these requirements.

Executive Order 12988—Civil Justice Reform

This direct final rule complies with the requirements of Executive Order 12988. Among other things, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation;

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria of section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This 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. A federalism summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department evaluated this direct final rule under Executive Order 13175 and the Department's consultation policies and determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's Tribal consultation policies is not required. The rule merely revises the Federal regulations to remove language made obsolete by a 1999 court ruling.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not a significant energy action as defined in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

National Environmental Policy Act

This direct final rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National

Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because this rule is covered by a categorical exclusion applicable to regulatory functions “that are of an administrative, financial, legal, technical, or procedural nature.” 43 CFR 46.210(i). In addition, the Department has determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act

This rule does not impose any new information collection burden under the Paperwork Reduction Act. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 1029–0048. This rule does not impose an information collection burden because the Department is not making any changes to the information collection requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601–612) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). As the Department is not required to publish a notice of proposed rulemaking for this direct final rule, the RFA does not apply.

Congressional Review Act

This rule is not a major rule under the Congressional Review Act (5 U.S.C. 804(2)). Specifically, the direct final rule: (a) will not have an annual effect on the economy of \$100 million or more; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than \$100 million per year. The rule does not have a

significant or unique effect on State, local, or Tribal governments, or the private sector. The rule merely revises the Federal regulations to remove an obsolete provision that is no longer used. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 817

Environmental protection, Reporting and recordkeeping requirements, Underground mining.

Leslie Shockley Beyer,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Department of the Interior amends 30 CFR part 817 as follows:

PART 817—PERMANENT PROGRAM PERFORMANCE STANDARDS—UNDERGROUND MINING ACTIVITIES

■ 1. The authority citation for part 817 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. In § 817.121:

■ a. Lift the suspension of paragraphs (c)(4)(i) through (iv); and

■ b. Revising paragraph (c)(4).

The revision reads as follows:

§ 817.121 Subsidence control.

* * * * *

(c) * * *

(4) *Rebuttable presumption of causation by subsidence.* In any determination whether damage to protected structures was caused by subsidence from underground mining, all relevant and reasonably available information will be considered by the regulatory authority.

* * * * *

[FR Doc. 2025–21444 Filed 11–26–25; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 870**

[Docket No. OSM–2025–0004 S1D1S
SS08011000 SX064A000 256S180110;
S2D2S SS08011000 SX064A000
25XS01520]

RIN 1029–AC88

Rescission of Fee Rates

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule revises the Federal regulations to rescind expired fee rates for coal produced for sale, transfer, or use from October 1, 2012, through September 30, 2021. New rates have been established and are in effect beginning October 1, 2021, through September 30, 2034.

DATES: The final rule is effective January 27, 2026, unless significant adverse comments are received by December 29, 2025. If significant adverse comments are received, notice will be published in the **Federal Register** before the effective date either withdrawing the rule or issuing a new final rule that responds to significant adverse comments.

ADDRESSES: You may submit comments by one of the following methods:

- **Electronically:** Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number [OSM–2025–0004]. Follow the instructions for submitting comments.
- **By hard copy:** Submit by U.S. mail to Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Attn: James Tyree, 1849 C Street NW, Mail Stop 4557, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: James Tyree, Chief, Division of Regulatory Support, (202) 208–4479, jtyree@osmre.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 regulations implementing the version of 30 U.S.C. 1232(a) that was in effect before the amendments made to that section by Public Law 117–58 (2021) are contained in 30 CFR 870.13(a). These regulations set fees for coal produced for sale, transfer, or use from October 1, 2012, through September 30, 2021. Upon reviewing these regulations, the Department of the Interior (Department) and the Office of Surface Mining Reclamation and Enforcement (OSMRE) have determined that this provision should be rescinded due to obsolescence resulting from the passage of time. The content of existing paragraph (b) of 30 CFR 870.13 will become the entire remaining section. No changes were made to the content of existing paragraph (b).

The Department has determined that this reason, independently and alone, justifies rescission of 30 CFR 870.13(a). The Department has no interest in maintaining a rule that is obsolete.

The Department is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA, 5 U.S.C. 551–559) generally requires agencies to engage in notice and comment rulemaking, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* § 553(b)(B). The Department has determined that notice and comment are unnecessary because this rule is noncontroversial; of a minor, technical nature; involves little agency discretion; and is unlikely to receive any significant adverse comments. Significant adverse comments are those that oppose the rescission of the rule and raise, alone or in combination, (1) reasons why the rescission of the rule is inappropriate, including challenges to the rescission’s underlying premise, or (2) serious unintended consequences of the rescission. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

Procedural Determinations

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule does not result in a taking of private property or otherwise have regulatory takings implications under Executive Order 12630. The rule rescinds an obsolete regulatory provision; therefore, the rule will not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the Nation’s regulatory system to promote predictability, reduce uncertainty, and

use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department developed this rule in a manner consistent with these requirements.

Executive Order 12988—Civil Justice Reform

This direct final rule complies with the requirements of Executive Order 12988. Among other things, this rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation;
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria of section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This 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. A federalism summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department evaluated this direct final rule under Executive Order 13175 and the Department’s consultation policies and determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department’s Tribal consultation policies is not required. The rule merely revises the

Federal regulations to remove obsolete regulatory language.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not a significant energy action as defined in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

National Environmental Policy Act

This direct final rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because this rule is covered by a categorical exclusion applicable to regulatory functions “that are of an administrative, financial, legal, technical, or procedural nature.” 43 CFR 46.210(i). In addition, the Department has determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act

This rule does not impose any new information collection burden under the Paperwork Reduction Act. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 1029–0063. This rule does not impose an information collection burden because the Department is not making any changes

to the information collection requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601–612) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). As the Department is not required to publish a notice of proposed rulemaking for this direct final rule, the RFA does not apply.

Congressional Review Act

This rule is not a major rule under the Congressional Review Act, 5 U.S.C. 804(2). Specifically, the direct final rule: (a) will not have an annual effect on the economy of \$100 million or more; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than \$100 million per year. The rule does not have a significant or unique effect on State,

local, or Tribal governments, or the private sector. The rule merely revises the Federal regulations to remove an obsolete provision that is no longer used. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 870

Coal, Fees, Reporting and recordkeeping requirements, Surface Mining, Underground mining.

Leslie Shockley Beyer,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Office of Surface Mining Reclamation and Enforcement amends 30 CFR part 870 as follows:

PART 870—ABANDONED MINE RECLAMATION FUND—FEE COLLECTION AND COAL PRODUCTION REPORTING

■ 1. The authority citation for part 870 continues to read as follows:

Authority: 28 U.S.C. 1746, 30 U.S.C. 1201 *et seq.*, and Public Law 105–277, 112 Stat. 2681.

■ 2. Revise § 870.13 to read as follows:

§ 870.13 Fee rates.

(a) Fees for coal produced for sale, transfer, or use from October 1, 2021, through September 30, 2034. Fees for coal produced for sale, transfer, or use from October 1, 2021, through September 30, 2034, are shown in the following table:

Type of fee	Type of coal	Amount of fee
(1) Surface mining fee.	Anthracite, bituminous, and subbituminous, including reclaimed.	(i) If value of coal is \$2.24 per ton or more, fee is 22.4 cents per ton.
(2) Underground mining fee.	Anthracite, bituminous, and subbituminous.	(ii) If value of coal is less than \$2.24 per ton, fee is 10 percent of the value.
(3) Surface and underground mining fee.	Lignite	(i) If value of coal is \$0.96 per ton or more, fee is 9.6 cents per ton.
(4) In situ coal mining fee.	All types other than lignite	(ii) If value of coal is less than \$0.96 per ton, fee is 10 percent of the value.
(5) In situ coal mining fee.	Lignite	(i) If value of coal is \$3.20 per ton or more, fee is 6.4 cents per ton.
		(ii) If value of coal is less than \$3.20 per ton, fee is 2 percent of the value.
		9.6 cents per ton based on Btus per ton in place equated to the gas produced at the site as certified through analysis by an independent laboratory.
		6.4 cents per ton based on the Btus per ton of coal in place equated to the gas produced at the site as certified through analysis by an independent laboratory.

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 874**

[Docket No. OSM–2025–0015; S1D1S SS08011000 SX064A000 256S180110; S2D2S SS08011000 SX064A000 25XS501520]

RIN 1029–AC99

General Reclamation Requirements

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule revises the Federal regulations to rescind language requiring compliance with the regulations when funding reclamation projects with prior balance replacement funds, which are moneys from the United States Treasury's General Fund that replaced State or Tribal share funds that were allocated before October 1, 2007, but never appropriated by Congress.

DATES: The final rule is effective January 27, 2026, unless significant adverse comments are received by December 29, 2025. If significant adverse comments are received, notice will be published in the **Federal Register** before the effective date either withdrawing the rule or issuing a new final rule that responds to significant adverse comments.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number OSM–2025–0015. Follow the instructions for submitting comments.
- *By hard copy:* Submit by U.S. mail to Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Attn: James Tyree, 1849 C Street NW, Mail Stop 4557, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: James Tyree, Chief, Division of Regulatory Support, (202) 208–4479, jtyree@osmre.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 regulations at 30 CFR 874.11 clarify that States and Tribes must comply with 30 CFR part 874 when funding reclamation projects with certain moneys distributed by the Office of Surface Mining Reclamation and Enforcement (OSMRE) under Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA). 30 CFR 874.11(b) refers to prior balance replacement funds, which are moneys from the United States Treasury's General Fund that replaced State or Tribal share funds that were allocated before October 1, 2007, but never appropriated by Congress. Section 411(h)(1) of SMCRA required OSMRE to distribute prior balance replacement funds to eligible States and Tribes for seven years, beginning October 1, 2008. As the distribution of prior balance replacement funds is complete, the Department of the Interior (Department) and OSMRE have determined that existing 30 CFR 874.11(b) should be rescinded because it is obsolete. To the extent States or Tribes may have any unspent prior balance replacement funds, those funds will be governed by the regulations that were in place at the time of the initial grant award.

The Department has determined that this reason, independently and alone, justifies rescinding 30 CFR 874.11(b). The Department has no interest in maintaining a rule that is obsolete.

The Department is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA, 5 U.S.C. 551–559) generally requires agencies to engage in notice and comment rulemaking, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* § 553(b)(B). The Department has determined that notice and comment are unnecessary because this rule is noncontroversial; of a minor, technical nature; involves little agency discretion; and is unlikely to receive any significant adverse comments. Significant adverse comments are those that oppose the rescission of the regulatory language and raise, alone or in combination, (1) reasons why the rescission of the regulatory language is inappropriate, including challenges to the rescission's underlying premise, or (2) serious unintended consequences of the rescission. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

Procedural Determinations

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule does not result in a taking of private property or otherwise have regulatory takings implications under Executive Order 12630. The rule revises the Federal regulations to remove obsolete regulatory language; therefore, the rule will not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the Nation's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department developed this rule in a manner consistent with these requirements.

Executive Order 12988—Civil Justice Reform

This direct final rule complies with the requirements of Executive Order 12988. Among other things, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation;

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria of section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This 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. A federalism summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department evaluated this direct final rule under Executive Order 13175 and the Department's consultation policies and determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's Tribal consultation policies is not required. The rule merely revises the Federal regulations to remove obsolete regulatory language.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not a significant energy action as defined in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

National Environmental Policy Act

This direct final rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because this rule is covered by a categorical exclusion applicable to regulatory functions “that are of an administrative, financial, legal, technical, or procedural nature.” 43 CFR 46.210(i). In addition, the Department has determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act

This rule does not impose any new information collection burden under the Paperwork Reduction Act. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 1029–0113. This rule does not impose an information collection burden because the Department is not making any changes to the information collection requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601–612) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). As the Department is not required to publish a notice of proposed rulemaking for this direct final rule, the RFA does not apply.

Congressional Review Act

This rule is not a major rule under the Congressional Review Act, 5 U.S.C. 804(2). Specifically, the direct final rule: (a) will not have an annual effect on the economy of \$100 million or more; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments, or the private sector. The rule merely revises the Federal regulations to remove obsolete regulatory language. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 874

Indians—lands, Surface mining, Underground mining.

Leslie Shockley Beyer,
Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Department of the Interior amends 30 CFR part 874 as follows:

PART 874—GENERAL RECLAMATION REQUIREMENTS

■ 1. The authority citation for part 874 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Revise § 874.11 to read as follows:

§ 874.11 Applicability.

You must comply with the requirements in this part for—

(a) Reclamation projects using moneys from the Fund; or

(b) Coal reclamation projects by certified States and Indian tribes required to maintain certification under section 411(a) of SMCRA and the agreement required by §§ 875.13(a)(3) and 875.14(b) of this chapter to maintain that certification.

[FR Doc. 2025–21450 Filed 11–26–25; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 875**

[Docket No. OSM–2025–0020; S1D1S
SS08011000 SX064A000 256S180110;
S2D2S SS08011000 SX064A000
25XS01520]

RIN 1029–AC97

Certification and Noncoal Reclamation

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule revises the Federal regulations to rescind language identifying obsolete funds as part of the moneys that the Office of Surface Mining Reclamation and Enforcement (OSMRE) must distribute to eligible States and Tribes each fiscal year. The existing regulations refer to prior balance replacement funds, which are moneys from the United States Treasury's General Fund that replaced State or Tribal share funds that were allocated before October 1, 2007, but never appropriated by Congress.

DATES: The final rule is effective January 27, 2026, unless significant adverse comments are received by December 29, 2025. If significant adverse comments are received, notice will be published in the **Federal Register** before the effective date either withdrawing the rule or issuing a new final rule that responds to significant adverse comments.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov> and search for Docket Number OSM–2025–0020. Follow the instructions for submitting comments.
- *By hard copy:* Submit by U.S. mail to Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Attn: James Tyree, 1849 C Street NW, Mail Stop 4557, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

James Tyree, Chief, Division of Regulatory Support, (202) 208–4479, jtyree@osmre.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 regulations at 30 CFR 875.16 prohibit certified and uncertified States and Tribes from expending certain moneys awarded to them by OSMRE under title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA) for the reclamation of sites and areas designated for remedial action under the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7901 *et seq.*) or that have been listed for remedial action under the Comprehensive Environmental Response Compensation and Liability Act of 1980 (42 U.S.C. 9601 *et seq.*). Existing 30 CFR 875.16(a) and (b)(2) refer to prior balance replacement funds, which are moneys from the United States Treasury's General Fund that replaced State or Tribal share funds that were allocated before October 1, 2007, but never appropriated by Congress. Section 411(h)(1) of SMCRA required OSMRE to distribute prior balance replacement funds to eligible States and Tribes for 7 years, beginning October 1, 2008. As the distribution of prior balance replacement funds is complete, the Department of the Interior

(Department) and OSMRE have determined that the reference to prior balance replacement funds in 30 CFR 875.16(a) should be removed and existing 30 CFR 875.16(b)(2) should be rescinded because they are obsolete. To the extent States or Tribes may have any unspent prior balance replacement funds, those funds will be governed by the regulations that were in place at the time of the initial grant award.

The Department has determined that these reasons, independently and alone, justify amending 30 CFR 875.16(a) and rescinding existing 30 CFR 875.16(b)(2) to remove the references to prior balance replacement funds. The Department has no interest in maintaining a rule that is obsolete.

The Department is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA, 5 U.S.C. 551–559) generally requires agencies to engage in notice and comment rulemaking, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* § 553(b)(B). The Department has determined that notice and comment are unnecessary because this rule is noncontroversial; of a minor, technical nature; involves little agency discretion; and is unlikely to receive any significant adverse comments. Significant adverse comments are those that oppose the amendment or rescission of the regulatory language and raise, alone or in combination, (1) reasons why the amendment or rescission of the regulatory language is inappropriate, including challenges to the amendment's or rescission's underlying premise, or (2) serious unintended consequences of the amendment or rescission. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

Procedural Determinations

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule does not result in a taking of private property or otherwise have regulatory takings implications under Executive Order 12630. The rule revises the Federal regulations to remove obsolete regulatory language; therefore, the rule will not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the Nation's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department developed this rule in a manner consistent with these requirements.

Executive Order 12988—Civil Justice Reform

This direct final rule complies with the requirements of Executive Order 12988. Among other things, this rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation;
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria of section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This 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. A federalism summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. The Department evaluated this direct final rule under Executive Order 13175 and the Department's consultation policies and determined that it has no substantial direct effects on federally recognized Indian Tribes and that consultation under the Department's Tribal consultation policies is not required. The rule merely revises the Federal regulations to remove obsolete regulatory language.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not a significant energy action as defined in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

National Environmental Policy Act

This direct final rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because this rule is covered by a categorical exclusion applicable to regulatory functions “that are of an administrative, financial, legal, technical, or procedural nature.” 43 CFR 46.210(i). In addition, the Department has determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Paperwork Reduction Act

This rule does not impose any new information collection burden under the Paperwork Reduction Act. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 1029–0103. This rule does not impose an information collection burden because the Department is not making any changes to the information collection requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601–612) requires an agency to prepare a regulatory flexibility analysis

for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. *See* 5 U.S.C. 603(a) and 604(a). As the Department is not required to publish a notice of proposed rulemaking for this direct final rule, the RFA does not apply.

Congressional Review Act

This rule is not a major rule under the Congressional Review Act, 5 U.S.C. 804(2). Specifically, the direct final rule: (a) will not have an annual effect on the economy of \$100 million or more; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments, or the private sector. The rule merely revises the Federal regulations to remove obsolete regulatory language. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 875

Indians—lands, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Leslie Shockley Beyer,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Department amends 30 CFR part 875 as follows:

PART 875—CERTIFICATION AND NONCOAL RECLAMATION

■ 1. The authority citation for part 875 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Amend § 875.16 by:

- a. Revising paragraph (a);
- b. Removing paragraph (b)(2); and
- c. Redesignating paragraph (b)(3) as paragraph (b)(2)

The revision reads as follows:

§ 875.16 Exclusion of certain noncoal reclamation sites.

(a) You, the uncertified State or Indian tribe, may not use moneys from the Fund for the reclamation of sites and areas designated for remedial action under the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7901 *et seq.*) or that have been listed for remedial action under the Comprehensive Environmental Response Compensation and Liability Act of 1980 (42 U.S.C. 9601 *et seq.*).

* * * * *

[FR Doc. 2025–21442 Filed 11–26–25; 8:45 am]

BILLING CODE 4310–05–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 381

[Docket No. 2025–CRB–0011–PBR (2023–2027) COLA (2026)]

Cost of Living Adjustment to Public Broadcasters Compulsory License Royalty Rate

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Final rule; cost of living adjustment.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) to the royalty rate that noncommercial radio stations at certain colleges, universities, and other educational institutions that are not affiliated with National Public Radio must pay for the use in 2026 of published nondramatic musical compositions in the SESAC Performing Rights, LLC (SESAC), and Global Music Rights, LLC, (GMR), repertoires pursuant to the statutory license under the Copyright Act for noncommercial broadcasting.

DATES:

Effective date: November 28, 2025.

Applicability dates: These rates are applicable to the period January 1, 2026, through December 31, 2026.

FOR FURTHER INFORMATION CONTACT:

Anita Brown, CRB Program Specialist, (202) 707–7658, crb@loc.gov.

SUPPLEMENTARY INFORMATION: Section 118 of the Copyright Act, title 17 of the United States Code, creates a statutory license for the use of published nondramatic musical works and published pictorial, graphic, and sculptural works in connection with noncommercial broadcasting.

On June 28, 2023, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under section 118 of the Copyright Act for the license period 2023–2027. *See* 88 FR 41827. Pursuant to these regulations, on or before December 1 of each year, the Judges shall publish in the **Federal Register** notice of the change in the cost of living and a revised schedule of the rates codified at § 381.5(c)(3) and (4) relating to compositions in the repertory of SESAC and GMR. The adjustment, fixed to the nearest dollar, shall be the greater of (1) the change in the cost of living as determined by the Consumer Price Index (all consumers, all items) (“CPI-U”) “during the period from the most recent index published prior to the previous notice to the most recent index published prior to December 1 of that year” or (2) 1.5%. 37 CFR 381.10.

The change in the cost of living as determined by the CPI-U during the period from the most recent index published prior to the previous notice, *i.e.*, before December 1, 2024, to the most recent index published before December 1, 2025, is 2.9%.¹ In accordance with 37 CFR 381.10(b), the Judges announce that the COLA for calendar year 2026 shall be 2.9%. Application of the 2.9% COLA to the 2025 rates for the performance of published nondramatic musical compositions in the repertory of SESAC and GMR—\$199 per station—results in an adjusted rate of \$205 per station, rounded to the nearest dollar.

List of Subjects in 37 CFR Part 381

Copyright, Music, Radio, Rates, Television.

Final Regulations

In consideration of the foregoing, the Judges amend part 381 of title 37 of the Code of Federal Regulations as follows:

¹ The CPI-U announced on October 24, 2025, by the Bureau of Labor Statistics in its *Consumer Price Index News Release—Consumer Price Index*, is available at <https://www.bls.gov/news.release/pdf/cpi.pdf> at Table 1. The Copyright Royalty Judges note that the October 24, 2025, publication is the most recent CPI-U published by the Secretary of Labor before December 1 of the preceding year of this COLA adjustment (*i.e.*, 2026). The Bureau of Labor statistics has explained “BLS could not collect October 2025 reference period survey data due to a lapse in appropriations.” *See* <https://www.bls.gov/bls/2025-lapse-revised-release-dates.htm> (last visited Nov. 25, 2025). The “change in the cost of living during the period from the most recent index published prior to the previous notice to the most recent index published prior to December 1” of this year, *i.e.*, the change from October 2024 to September 2025, is 2.9% ((324.800–315.664)/315.664).

PART 381—USE OF CERTAIN COPYRIGHTED WORKS IN CONNECTION WITH NONCOMMERCIAL EDUCATIONAL BROADCASTING

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 17 U.S.C. 118, 801(b)(1) and 803.

■ 2. Section 381.5 is amended by revising paragraphs (c)(3)(iv) and (c)(4)(iv) as follows:

§ 381.5 Performance of musical compositions by public broadcasting entities licensed to colleges and universities.

- * * * * *
- (c) * * *
- (3) * * *
- (iv) 2026: \$205 per station.
- * * * * *
- (4) * * *
- (iv) 2026: \$205 per station.
- * * * * *

Dated: November 25, 2025.

Christina L. Shifton,

Interim Chief Copyright Royalty Judge.

[FR Doc. 2025–21579 Filed 11–26–25; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2024–0608; FRL–12597–02–R8]

Air Plan Approval; Montana; Regional Haze Plan for the Second Implementation Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a regional haze state implementation plan (SIP) revision submitted by the State of Montana on August 10, 2022 (Montana’s 2022 SIP submission), as satisfying applicable requirements under the Clean Air Act (CAA) and the EPA’s Regional Haze Rule (RHR) for the program’s second implementation period. The EPA is also finalizing approval of the prong 4 visibility portion of Montana’s October 1, 2018, Infrastructure SIP submission for the 2015 ozone National Ambient Air Quality Standard (NAAQS). The EPA is taking this action pursuant to the CAA.

DATES: This rule is effective on December 29, 2025.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2024–0608. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT:

Amrita Singh, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6103; email address: singh.amrita@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document “we,” “us,” and “our” means the EPA.

Table of Contents

- I. What is being addressed in this document?
- II. Background
- III. Public Comments and EPA Responses
- IV. Final Action
- V. Statutory and Executive Order Reviews

I. What is being addressed in this document?

The EPA is approving a SIP revision submitted by the State of Montana to the EPA on August 10, 2022, addressing the requirements of the second implementation period of the RHR. As required by section 169A of the CAA, the RHR calls for state and federal agencies to work together to improve visibility in 156 national parks and wilderness areas. The rule requires the states, in coordination with the EPA, the National Park Service, Fish and Wildlife Service, the Forest Service, and other interested parties, to develop and implement air quality protection plans to reduce the pollution that causes visibility impairment in mandatory Class I Federal areas. Visibility impairing pollutants include fine and coarse particulate matter (PM) (*e.g.*, sulfates, nitrates, organic carbon, elemental carbon, and soil dust) and their precursors (*e.g.*, sulfur dioxide (SO₂), oxides of nitrogen (NO_x), and, in some cases, volatile organic compounds (VOC) and ammonia (NH₃)). As discussed in further detail in our proposed rule, this document, and the accompanying Response to Comments

(RTC) document, the EPA finds that Montana submitted a regional haze SIP that meets all the regional haze requirements for the second implementation period. The State's submission, the proposed rule, and the RTC document can be found in the docket for this action.

II. Background

On August 10, 2022, Montana submitted a revision to its SIP to address its regional haze obligations for the second implementation period (2018–2028). Montana made this revision to satisfy the requirements of the CAA's regional haze program pursuant to CAA sections 169A and 169B and 40 Code of Federal Regulations (CFR) 51.308.

On September 11, 2025, the EPA proposed to approve Montana's 2022 SIP submission.¹ Specifically, the EPA proposed to approve Montana's 2022 SIP submission as satisfying the requirements of 40 CFR 51.308(f)(1): calculations of baseline, current, and natural visibility conditions, progress to date, and the uniform rate of progress; 40 CFR 51.308(f)(2): long-term strategy; 40 CFR 51.308(f)(3): reasonable progress goals; 40 CFR 51.308(f)(4): reasonably attributable visibility impairment; 40 CFR 51.308(f)(5) and 40 CFR 51.308(g): progress report requirements; 40 CFR 51.308(f)(6): monitoring strategy and other implementation plan requirements; and 40 CFR 51.308(i): Federal Land Manager (FLM) consultation. Our public comment period closed on October 14, 2025.

The September 11, 2025, proposed rule provided background on the requirements of the CAA and RHR, a summary of Montana's regional haze SIP submittal and related EPA actions, and the EPA's rationale for its proposed action. That background and rationale will not be restated here. For the reasons stated in the proposed rule, this document, and in the accompanying RTC document, the EPA concludes that Montana's 2022 SIP submission meets the requirements of the CAA and RHR.

III. Public Comments and EPA Responses

The public comment period on the proposal closed on October 14, 2025. During the public comment period, we received 16 comments on our proposal: 1 in support and 15 in opposition. The commenters were: Conservation Groups,² the Mid-Atlantic/Northeast Visibility Union (MANEVU),³ Cabinet

Resource Group,⁴ Talen Montana,⁵ and eight individual commenters.⁶ The full text of comments received is included in the publicly posted docket associated with this action at <https://www.regulations.gov>. Our RTC document, which is also included in the docket associated with this action, provides detailed responses to all significant comments received.

IV. Final Action

For the reasons stated in the preamble to the proposed rule, in the RTC document, and in this document, we are approving Montana's 2022 SIP submission. Specifically, we are approving Montana's 2022 SIP submission relating to CAA 169A:

- Calculations of baseline, current, and natural visibility conditions, progress to date, and uniform rate of progress (40 CFR 51.308(f)(1));
- Long-term strategy (40 CFR 51.308(f)(2));
- Reasonable progress goals (40 CFR 51.308(f)(3));
- Reasonably attributable visibility impairment (40 CFR 51.308(f)(4));
- Progress report requirements (40 CFR 51.308(f)(5) and 40 CFR 51.308(g));
- Monitoring strategy and other implementation plan requirements (40 CFR 51.308(f)(6));
- FLM consultation (40 CFR 51.308(i)).

In addition, we are approving the prong 4 visibility portion of Montana's October 1, 2018 Infrastructure SIP submission for the 2015 ozone NAAQS.

V. Statutory and Executive Order Reviews

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

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025)

because State Implementation Plan approvals under the CAA are exempt from review under Executive Order 12866;

- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandate or significantly or uniquely affect small governments, described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 27, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

¹ 90 FR 43958 (September 11, 2025).

² Letter dated October 14, 2025.

³ Letter dated October 14, 2025.

⁴ Letter dated October 14, 2025.

⁵ Letter dated October 14, 2025.

⁶ Letters dated from September 29, 2025 to October 14, 2025.

List of Subjects in 40 CFR Part 52

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

Dated: November 17, 2025.

Cyrus M. Western,
Regional Administrator, Region 8.

For the reasons stated in the preamble, the Environmental Protection

Agency is amending 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart BB—Montana

■ 2. In § 52.1370:

■ a. Amend the table in paragraph (e) by:

■ i. Under the center heading “(1) Statewide”, adding the entries “Montana Regional Haze State Implementation Plan” and “Interstate Transport Requirements of the CAA, section 110(a)(2)(D)(i)(II) prong 4, for the 2015 Ozone NAAQS” after the entry “Interstate Transport Requirements of the CAA, section 110(a)(2)(D)(i)(I), for the 2015 Ozone NAAQS” to read as follows:

§ 52.1370 Identification of plan.

* * * * *
(e) * * *

Title/subject	State effective date	Notice of final rule date	NFR citation
(1) Statewide			
* * * * *			
Montana Regional Haze State Implementation Plan	8/10/2022	11/28/2025	90 FR [insert Federal Register page where the document begins].
Interstate Transport Requirements of the CAA, section 110(a)(2)(D)(i)(II) prong 4, for the 2015 Ozone NAAQS.	8/22/2018	11/28/2025	90 FR [insert Federal Register page where the document begins].
* * * * *			

[FR Doc. 2025–21340 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 423

[EPA–HQ–OW–2009–0819; FRL–8794.3–03–OW]

RIN 2040–AG48

Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category—Initial Notification Date Extension; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Because the U.S. Environmental Protection Agency (EPA) received adverse comment, it is withdrawing the direct final rule entitled, “Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category—Initial Notification Date

Extension,” published in the **Federal Register** on October 2, 2025.

DATES: Effective November 28, 2025, the EPA withdraws the direct final rule published at 90 FR 47617, on October 2, 2025.

FOR FURTHER INFORMATION CONTACT:

Richard Benware, Engineering and Analysis Division Office of Water (Mail Code 4303T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–1369; email address: benware.richard@epa.gov.

SUPPLEMENTARY INFORMATION: Because the EPA received adverse comment, the Agency is withdrawing the direct final rule entitled, “Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category—Initial Notification Date Extension,” published on October 2, 2025 (90 FR 47617). The EPA stated in that direct final rule that if it received adverse comment by November 3, 2025, the direct final rule would not take effect, and the EPA would publish a timely withdrawal in the **Federal Register**. Because the EPA subsequently received adverse comment on that direct

final rule, it is withdrawing the direct final rule.

The EPA published a companion proposed rule on the same day as the direct final rule (90 FR 47693). The proposed rule invited comment on the substance of the direct final rule (as well as on additional subjects). The EPA will address those comments in a subsequent final action, which will be based on the companion proposed rule. As stated in the direct final rule and the companion proposed rule, the EPA will not institute a second comment period on this subject.

List of Subjects in 40 CFR Part 423

Environmental protection, Electric power generation, Power facilities, Waste treatment and disposal, Water pollution control.

Lee Zeldin,
Administrator.

■ Accordingly, as of November 28, 2025], the EPA withdraws the direct final rule amending 40 CFR part 423, which published at 90 FR 47617, on October 2, 2025.

[FR Doc. 2025–21426 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 405, 410, 414, 424, 425, 427, 428, 495, and 512****[CMS–1832–CN2]****RIN 0938–AV50****Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Correction****AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).**ACTION:** Final rule; correction.

SUMMARY: This document corrects technical errors in the final rule that appeared in the November 5, 2025 **Federal Register** (90 FR 49266) titled “Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program” (hereinafter referred to as the CY 2026 PFS final rule), specifying finalized changes to the Medicare physician fee schedule (PFS) that is applicable for calendar year (CY) 2026, and other changes to Medicare Part B payment policies, as well as proposals regarding other Medicare payment policies.

DATES: *Effective date:* This correcting document is effective November 28, 2025.

FOR FURTHER INFORMATION CONTACT: Emily Yoder (410) 786–104 or MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to skin substitutes.

SUPPLEMENTARY INFORMATION:**I. Background**

In FR Doc. 2025–19787 of November 5, 2025, the CY 2026 PFS final rule (90 FR 49266), there were technical errors that are identified in this correcting document.

II. Summary of Errors

On pages 49493, 49496, 49501, 49504, and 49506 through 49509, we inadvertently made typographical and technical errors in our discussion of the payment for skin substitutes.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 1871(e)(1)(B)(i) of the Act mandates a 30-day delay in effective date after issuance or publication of a rule. Section 1871(b)(2)(C) of the Act provides an exception from the notice and 60-day comment period and delay in effective date requirements of the Act, under the good cause standard set forth in 5 U.S.C. 553(b)(B). Section 1871(e)(1)(B)(ii) of the Act provides an exception from the delay in effective date requirements of the Act as well. Section 553(b)(B) authorizes an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. In addition, section 1871(e)(1)(B)(ii) of the Act allows the agency to avoid the 30-day delay in effective date where the waiver is necessary to comply with statutory requirements or such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects technical and typographical errors in the payment for skin substitutes provisions of the CY 2026 PFS final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies that were proposed, subject to notice and comment procedures, and adopted in the CY 2026 PFS final rule. As a result, the corrections made through this document are intended to resolve inadvertent errors in the discussion of the skin substitutes policies so that the CY 2026 PFS final rule accurately reflects the policies adopted therein.

In addition, even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2026 PFS final rule or delaying the effective date of the corrections are unnecessary because we

are not making any substantive revisions to the CY 2026 PFS final rule, but rather, we are simply correcting the **Federal Register** documents to reflect the skin substitutes policies that we previously proposed, received public comment on, and subsequently finalized in the CY 2026 PFS final rule. Further comment is not needed to inform our decision to rectify the ministerial errors noted in this final rule and correction. For these reasons, we believe there is good cause to waive notice and comment and delay in effective date, even if they were required.

IV. Correction of Errors

In FR Doc. 2025–19787 of November 5, 2025 (90 FR 49266), make the following corrections:

1. On page 49493,
 - a. Second column, second full paragraph, line 33 and 34, the phrase “as a drug or as a biological product” is corrected to read “as a biological product”;
 - b. Third column, first partial paragraph, line 10, the phrase “as a drug or as a biological product” is corrected to read “as a biological product”.
2. On page 49496, first column, fourth full paragraph, line 5, “as a drug or as a biological product” is corrected to read “as a biological product”.
3. On page 49501, second column, first partial paragraph, lines 21 through 25, the phrase “the file titled ‘Skin Substitute Products by FDA Regulatory Category’ on the CMS website under downloads for the CY 2026 PFS final rule at” is corrected to read “Addendum B of the PFS proposed rule’ on the CMS website under downloads for the CY 2026 PFS proposed rule at”.
4. On page 49504,
 - a. First column,
 - (1) First full paragraph, line 2, the phrase “an initial payment rate” is corrected to read “an initial proposed payment rate”.
 - (2) Second full paragraph, line 6, the phrase “quarter of data.” is corrected to read “quarter of data at the time of the proposed rule.”.
 - b. Second column, second full paragraph, line 3, the phrase “\$125 per square centimeter” is corrected to read “\$125/cm²”.
5. On page 49506, third column, first full paragraph, line 8, the phrase “\$125.38 rate” is corrected to read “\$125.38/cm² rate”.
6. On page 49507, second column,
 - a. First partial paragraph, line 9, the phrase “\$127.28/cm².” is corrected to read “\$127.14/cm²”.
 - b. Second full paragraph, lines 8 through 17 the phrase “the exception of updates to several code classifications

and updated with the most recent data available as of the time of drafting this final rule, which resulted in a final payment rate for CY 2026 of \$127.19/cm². Specifically, we used 2026 MUC data (based on 2024 claims data) for the fourth quarter 2024 ASP data, weight by hospital outpatient claims volume.” is corrected to read “the exception of updating the calculation with more recent utilization data available as of the time of drafting this final rule, which resulted in a final payment rate for CY

2026 of \$127.14/cm². Specifically, we also used fourth quarter 2024 ASP data and 2026 MUC data (based on 2024 claims data), when ASP data was not available, weighted by more up to date hospital outpatient claims volume.”.

7. On page 49508, second column, first partial paragraph, lines 4 and 5, the phrase “a skin substitute is approved as a drug or as a biological product” is corrected to read “a skin substitute is approved as a biological product”.

8. On page 49509, third column, first partial paragraph,

a. Line 8, the figure “\$127.28/cm²” is corrected to read “\$127.14/cm²”.

b. Lines 11 and 12, the phrase “This rate reflects updates to several code classifications and uses” is corrected to read “This rate uses”.

Wilma M. Robinson,

*Deputy Executive Secretary to the
Department, Department of Health and
Human Services.*

[FR Doc. 2025–21458 Filed 11–26–25; 8:45 am]

BILLING CODE 4120–01–P

Proposed Rules

Federal Register

Vol. 90, No. 227

Friday, November 28, 2025

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2025-5033; Project Identifier MCAI-2025-00795-R]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model H160-B helicopters. This proposed AD was prompted by a report of a tail rotor drive rear shaft that came into contact with its rear damper during a flight test. This proposed AD would require repetitive visual inspections of the rear damper and, depending on the results, corrective actions. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by January 12, 2026.

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

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

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

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

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

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2025-5033; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except

Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

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

FOR FURTHER INFORMATION CONTACT:

Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946-4116; email: adam.hein@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA-2025-5033; Project Identifier MCAI-2025-00795-R” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner.

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

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2025-0098, dated April 29, 2025 (EASA AD 2025-0098) (also referred to as the MCAI), to correct an unsafe condition on Airbus Helicopters Model H160-B helicopters. The MCAI advises of a report that the tail rotor drive rear shaft of the tail drive line had come in contact with its rear damper during a flight test. This contact is expected only when the helicopter is on the ground, during transition phases of either accelerating (ramp up) or decelerating (ramp-down), when passing the shaft critical mode. This unsafe condition, if not detected and corrected, could result in degradation of the rear damper and its support, loss of the rear damper function, failure of the tail rotor drive rear shaft, and consequent loss of yaw control of the helicopter.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2025-5033.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025-0098, which specifies procedures for repetitive visual inspections of the two radii in the top area of the rear damper, the hard chrome oxide deposit on the friction bush located under the rear damper, and the rear damper supports for cracks and loose or missing fasteners

and, depending on the results, performing further inspections, replacing the rear damper, or contacting the manufacturer for further corrective actions. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA’s Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2025–0098, described

previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD. See “Differences Between this Proposed AD and the MCAI” for a discussion of the general differences included in this AD.

Differences Between This Proposed AD and the MCAI

Where the MCAI specifies contacting Airbus Helicopters for repair instructions, this proposed AD would require using a method approved by the FAA, EASA, or Airbus Helicopters’ EASA Design Organization Approval.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some CAA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2025–0098 by reference in the FAA

final rule. This proposed AD would, therefore, require compliance with EASA AD 2025–0098 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2025–0098 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2025–0098. Material required by EASA AD 2025–0098 for compliance will be available at *regulations.gov* under Docket No. FAA–2025–5033 after the FAA final rule is published.

Costs of Compliance

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

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Visual inspection of rear damper	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$765

The FAA estimates the following costs to do any replacements that would be required based on the results of the

proposed inspection. The agency has no way of determining the number of

helicopters that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace rear damper	8 work-hours × \$85 per hour = \$680	\$22,647	\$23,327

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

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA

with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2025–5033; Project Identifier MCAI–2025–00795–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 12, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model H160–B helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 6510, Tail Rotor Drive Shaft.

(e) Unsafe Condition

This AD was prompted by a report of a tail rotor drive rear shaft of the tail drive line coming into contact with its rear damper during a flight test. The FAA is issuing this AD to detect and correct the tail rotor drive rear shaft contacting the rear damper during flight. The unsafe condition, if not addressed, could result in degradation of the rear damper and its support, loss of the rear damper function, failure of the tail rotor drive rear shaft, and consequent loss of yaw control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2025–0098, dated April 29, 2025 (EASA AD 2025–0098).

(h) Exceptions to EASA AD 2025–0098

(1) Where EASA AD 2025–0098 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2025–0098 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(3) Where paragraph (2) of EASA AD 2025–0098 specifies contacting AH (Airbus Helicopters) to obtain approved instructions,

this AD requires actions done in accordance with a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus Helicopters' EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) This AD does not adopt the “Remarks” section of EASA AD 2025–0098.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(j) Additional Information

For more information about this AD, contact Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4116; email: adam.hein@faa.gov.

(k) 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) European Union Aviation Safety Agency (EASA) AD 2025–0098, dated April 29, 2025.

(ii) [Reserved]

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

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

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

Issued on November 24, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–21434 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–1362; Project Identifier MCAI–2025–00062–G]

RIN 2120–AA64

Airworthiness Directives; Schempp-Hirth Flugzeugbau GmbH Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: The FAA is revising a notice of proposed rulemaking (NPRM) that would have applied to certain Schempp-Hirth Flugzeugbau GmbH (Schempp-Hirth) Model CIRRUS gliders. This action revises the NPRM by changing references to the affected glider model from CIRRUS to STANDARD CIRRUS throughout the proposed airworthiness directive (AD). The FAA is proposing this AD to address the unsafe condition on these products. The FAA is requesting comments on this SNPRM.

DATES: The FAA must receive comments on this SNPRM by January 12, 2026.

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

- *Federal eRulemaking Portal:* Go to regulations.gov. 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–2025–1362; 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 SNPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For SCHEMPP–HIRTH Flugzeugbau GmbH material identified in this proposed AD, contact Schempp-Hirth, Krehenstraße 25, 73230 Kirchheim unter Teck, Germany; phone: +49 7021 7298–0; email: info@schempp-hirth.com; website: schempp-hirth.com.

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

FOR FURTHER INFORMATION CONTACT: Peter Schmitt, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (206) 231-3377; email: peter.a.schmitt@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–1362; Project Identifier MCAI–2025–00062–G” 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 again revise 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](https://www.regulations.gov), including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this SNPRM.

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 SNPRM 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 SNPRM, 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 SNPRM. Submissions containing CBI should be sent to Peter Schmitt, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury,

NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain Schempp-Hirth Model CIRRUS gliders. The NPRM was published in the **Federal Register** on July 22, 2025 (90 FR 34391). The NPRM was prompted by European Union Aviation Safety Agency (EASA) AD 2024–0242R1, dated January 17, 2025, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2024–0242R1) (also referred to as the MCAI). The MCAI states that occurrences were reported of a broken outer race in the lower ball bearing installed on the all-moving horizontal tailplane drive fitting. This condition, if not addressed, could lead to the tailplane drive jamming and loss of control of the glider.

In the NPRM, the FAA proposed to require inspecting the elevator drive fitting to determine the type of lower ball bearing installed and, depending upon the results, replacing the lower ball bearing with a serviceable part.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–1362.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, a commenter noted that the NPRM referenced the incorrect glider model. The SNPRM revises the NPRM by updating the reference to the affected Schempp-Hirth glider model from CIRRUS to STANDARD CIRRUS. Neither the MCAI nor the service information has been revised since the NPRM was published. This SNPRM was prompted by the FAA’s determination that the affected glider model referenced in the NPRM was incorrect and needed to be changed. The FAA is proposing this AD to address the unsafe condition on these products.

Comments

The FAA received one comment from an individual commenter. The following presents the comment received on the NPRM and the FAA’s response to the comment.

Request To Correct Glider Model Applicability

An individual commenter requested that the FAA revise the proposed AD by

changing the referenced applicability to Schempp-Hirth Model STANDARD CIRRUS sailplanes rather than Schempp-Hirth Model CIRRUS sailplanes. The commenter noted that the CIRRUS sailplane is a different type of glider model than the STANDARD CIRRUS sailplane with a different type of elevator.

The FAA agrees with the commenter’s request and has revised this proposed AD as requested.

FAA’s Determination

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

Certain changes described above expand the scope of the NPRM. As a result, it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed SCHEMPP–HIRTH Flugzeugbau GmbH Technical Note No. 278–25, Revision 1, dated July 9, 2024, which specifies procedures for inspecting the elevator drive fitting to determine which type of lower ball bearing is installed, and depending on the results, replacing the lower ball bearing with a serviceable part.

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 SNPRM

This proposed AD would require accomplishing the actions specified in the material already described.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 17 gliders 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
Inspect elevator drive fitting or records review to determine if affected part is installed.	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$1,445

The FAA estimates the following costs to do any necessary replacements that would be required based on the

results of the proposed inspection. The agency has no way of determining the

number of gliders that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace elevator drive lower ball bearing	1 work-hour × \$85 per hour = \$85	\$35	\$120

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Schempp-Hirth Flugzeugbau GmbH: Docket No. FAA-2025-1362; Project Identifier MCAI-2025-00062-G.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 12, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Schempp-Hirth Flugzeugbau GmbH Model STANDARD CIRrus gliders, serial numbers 21, 23, 27, 30, 32, 33, 34, 36 through 52, and 54 through 120, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5520, Elevator Structure.

(e) Unsafe Condition

This AD was prompted by reports of a broken outer race component of the lower ball bearing installed in the all-moving horizontal tailplane drive fitting. The FAA is issuing this AD to address this unsafe condition. The unsafe condition, if not

addressed, could result in the tailplane drive jamming and loss of control of the glider.

(f) Compliance

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

(g) Definitions

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

(1) An "affected part" is as identified in SCHEMPP-HIRTH Flugzeugbau GmbH Technical Note No. 278-25, Revision 1, dated July 9, 2024 (SCHEMPP-HIRTH TN No. 278-25, Revision 1): EL6 lower ball bearing (identified as type 1a) or self-aligning lower ball bearing (identified as type 1b) of the elevator drive fitting.

(2) A "serviceable part" is as identified in SCHEMPP-HIRTH TN No. 278-25, Revision 1: Lower bearing ring with inner bronze bushing having part number HS4-30.013/1 (identified as type 1d).

(h) Required Actions

(1) Within 4 months after the effective date of this AD, inspect the elevator drive fitting to determine if an affected part is installed, in accordance with the instructions of Actions 1. in SCHEMPP-HIRTH TN No. 278-25, Revision 1. A review of glider maintenance records instead of this inspection is acceptable provided it can be conclusively determined from that review if an affected part is installed.

(2) If, during the inspection or maintenance records review required by paragraph (h)(1) of this AD, it is determined that an affected part is installed, within 4 months after the effective date of this AD, replace the affected part with a serviceable part in accordance with the instructions of Actions 2. of SCHEMPP-HIRTH TN No. 278-25, Revision 1.

(i) Parts Installation Prohibition

As of the effective date of this AD, do not install an affected part as defined in paragraph (g)(1) of this AD on any glider.

(j) Alternative Methods of Compliance (AMOCs)

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

AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Peter Schmitt, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (206) 231-3377; email: peter.a.schmitt@faa.gov.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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) SCHEMPP-HIRTH Flugzeugbau GmbH Technical Note No. 278–25, Revision 1, dated July 9, 2024.

(ii) [Reserved]

(3) For SCHEMPP-HIRTH Flugzeugbau GmbH material identified in this AD, contact Schempp-Hirth Flugzeugbau GmbH, Kребенstraße 25, 73230 Kirchheim unter Teck, Germany; phone: +49 7021 7298-0; email: info@schempp-hirth.com; website: schempp-hirth.com.

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

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

Issued on November 24, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–21409 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–5034; Project Identifier MCAI–2025–00951–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, and AS332L2 helicopters. This proposed AD was prompted by a report of rupture of the scissors link of the rotating swashplate assembly due to a seized ball joint-cups assembly. This proposed AD would require replacing the rotor shaft assembly, modifying the rotating swashplate assembly to replace each of the three ball joint-cups assemblies with one-piece self-lubricated spherical bearings, and modifying the scissors hinges and swashplate trunnions on the main rotor, as applicable, and applying an anti-corrosion agent, if applicable. This proposed AD would prohibit installing a main rotor hub (MRH) assembly or rotor shaft assembly on a helicopter unless certain requirements are met. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by January 12, 2026

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

- **Federal eRulemaking Portal:** Go to regulations.gov. 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–2025–5034; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory

continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADS@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

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

FOR FURTHER INFORMATION CONTACT:

Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4116; email: adam.hein@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–5034; Project Identifier MCAI–2025–00951–R” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or

responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, issued EASA AD 2024–0168, dated August 22, 2024 (EASA AD 2024–0168), to correct an unsafe condition on Airbus Helicopters Model AS 332 C, AS 332 C1, AS 332 L, AS 332 L1, and AS 332 L2 helicopters. The MCAI states that an occurrence was reported of rupture of the scissors link of the rotating swashplate assembly resulting from a seized ball joint-cups assembly. Subsequent investigation revealed the following probable causes: the cups and ball joint that are normally paired were unpaired or mixed during an overhaul; and the cups and ball joint assembly had not been properly lubricated during overhaul. In addition, the cups and the ball joint are made of tungsten carbide, whose failure mode can cause a sudden seizure of the assembly. This condition, if not addressed, could lead to loss of connection between rotor shaft and rotating swashplate and consequent loss of control of the helicopter.

EASA AD 2024–0168 specified a modification to replace the ball joint-cups assembly with a one-piece self-lubricated spherical bearing and specified modification instructions for in-service helicopters. EASA then superseded EASA AD 2024–0168 and issued EASA AD 2025–0116, dated May 19, 2025 (EASA AD 2025–0116) (also referred to as the MCAI). The MCAI states that since EASA AD 2024–0168 was issued, it was identified that the original service information did not provide instructions to apply anti-corrosion agent on the parts during installation, and Airbus Helicopters

revised the service information to address that omission. The MCAI partially retains the requirements of EASA AD 2024–0168 and specifies additional work.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–5034.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2025–0116, which specifies procedures for replacing the rotor shaft assembly, modifying the rotating swashplate assembly, or replacing the MRH assembly as an alternative action for certain helicopters, as applicable. EASA AD 2025–0116 specifies procedures for certain helicopters to incorporate modification 0743046 either before or concurrently with the modification of the rotating swashplate assembly. EASA AD 2025–0116 also specifies procedures for applying anti-corrosion agent on the parts, as applicable. EASA AD 2025–0116 prohibits installing a MRH assembly or a rotor shaft assembly unless it is a post-mod 0728849 configuration.

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

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require Group 1 helicopters (as defined in the MCAI) to replace the rotor shaft assembly, Group 2 helicopters (as defined in the MCAI) to modify the rotating swashplate assembly to replace each of the three ball joint-cups

assemblies with one-piece self-lubricated spherical bearings or replace the MRH assembly with an MRH assembly in post-mod 0728849 and post-mod 0743046 configurations, and AS332C and AS332L helicopters to modify the scissors hinges and swashplate trunnions on the main rotor, as applicable. This proposed AD would also require Group 3 helicopters (as defined in the MCAI) to apply an anti-corrosion agent, if applicable. This proposed AD would prohibit installing a main rotor hub (MRH) assembly or rotor shaft assembly on a helicopter unless certain requirements are met.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA incorporates EASA AD 2025–0116 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2025–0116 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2025–0116 does not mean that operators need comply only with that section. For example, where the AD requirement refers to "all required actions and compliance times," compliance with this AD requirement is not limited to the section titled "Required Action(s) and Compliance Time(s)" in EASA AD 2025–0116. Material referenced in EASA AD 2025–0116 for compliance will be available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–5034 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 12 helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace three ball joint-cups assemblies	3 work-hours × \$85 per hour = \$255	\$9,861	\$10,116	\$121,392.
Apply anti-corrosion agent	3 work-hours × \$85 per hour = \$255	0	0	Up to \$3,060.

The FAA has received no definitive data on which to base the cost estimates for replacing the rotor shaft assembly with a rotor shaft assembly that has incorporated modifications 0743714 and 0728849, modifying the rotating swashplate assembly to incorporate modification 0743046, or for the optional action of replacing the MRH assembly with an MRH assembly that has incorporated modifications 0728849 and 0743046 specified in this proposed AD.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2025–5034; Project Identifier MCAI–2025–00951–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 12, 2026.

(b) Affected ADs

None.

(c) Applicability

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

(d) Subject

Joint Aircraft System Component (JASC) Code 6230, Main Rotor Mast/Swashplate.

(e) Unsafe Condition

This AD was prompted by a report of the rupture of the scissors link of the rotating swashplate assembly due to a seized ball joint-cups assembly. The FAA is issuing this AD to prevent the ball joint-cups assembly from seizing. This condition, if not addressed, could lead to loss of connection between rotor shaft and rotating swashplate and consequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2025–0116, dated May 19, 2025 (EASA AD 2025–0116).

(h) Exceptions to EASA AD 2025–0116

(1) Where EASA AD 2025–0116 refers to September 5, 2024 (the effective date of EASA AD 2024–0168), this AD requires using the effective date of this AD.

(2) Where EASA AD 2025–0116 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraph (3) of EASA AD 2025–0116 refers to "modify that helicopter in accordance with the instructions of the Airbus Helicopter SB 62.00.05", this AD replaces that text with "modify that helicopter in accordance with the instructions of the Societe Nationale Industrielle Aeronautique Service Bulletin No. 62.05, Revision 2".

(4) This AD does not adopt the "Remarks" section of EASA AD 2025–0116.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2025–0116 specifies to submit certain information to the manufacturer, this AD does not require that action.

(j) Special Flight Permits

Special flight permits are prohibited.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Additional Information

For more information about this AD, contact Adam Hein, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4116; email: adam.hein@faa.gov.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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) European Union Aviation Safety Agency (EASA) AD 2025–0116, dated May 19, 2025.

(ii) Reserved

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

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

(5) You may view this material at the National Archives and Records

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

Issued on November 24, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–21437 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–5037; Project Identifier AD–2025–00212–A]

RIN 2120–AA64

Airworthiness Directives; Textron Aviation, Inc. (Type Certificate Previously Held by Cessna Aircraft Company) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Textron Aviation, Inc., Model 525B airplanes. This proposed AD was prompted by the manufacturer's revision of the aircraft maintenance manual (AMM) to introduce more restrictive inspection intervals. This proposed AD would require revising the Airworthiness Limitations Section (ALS) of the existing AMM or instructions for continued airworthiness (ICA) and the existing approved maintenance or inspection program, as applicable. 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 January 12, 2026.

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

- *Federal eRulemaking Portal:* Go to regulations.gov. 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–2025–5037; 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.

FOR FURTHER INFORMATION CONTACT:

Soban Saeed, Aviation Safety Engineer, FAA, 1801 South Airport Road, Wichita, KS 67209; phone: (316) 946–4123; email: CCB-COS@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–5037; Project Identifier AD–2025–00212–A” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may revise 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 Soban Saeed, Aviation Safety Engineer, FAA, 1801 South Airport Road, Wichita, KS 67209. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA was notified by Textron Aviation that the existing Model 525B AMM contained incorrect inspection intervals for airworthiness limitation tasks for Chapter 54—Nacelle/Pylons and Chapter 55—Stabilizers. The incorrect inspection intervals were introduced during a technical manual update. The FAA is issuing this AD to prevent undetected cracks in the engine mount and vertical stabilizer front and rear spar caps. The unsafe conditions, if not addressed, could result in reduced structural integrity and consequent reduced controllability of the airplane.

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.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the ALS of the existing AMM or ICA and the existing approved maintenance or inspection program, as applicable, by incorporating the actions and associated thresholds and intervals specified in table 1 to paragraph (g) of this proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 601 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
Revise the ALS	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$51,085

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Textron Aviation Inc.: Docket No. FAA–2025–5037; Project Identifier AD–2025–00212–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 12, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Textron Aviation, Inc. (Type Certificate previously held by Cessna Aircraft Company) Model 525B airplanes, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5530, Vertical Stabilizer Structure; 5415, Nacelle/Pylon, Attach Fittings.

(e) Unsafe Condition

This AD was prompted by the manufacturer's revision of the aircraft maintenance manual (AMM) to introduce more restrictive inspection intervals. The FAA is issuing this AD to prevent undetected cracks in the engine mount and vertical stabilizer front and rear spar caps. The unsafe conditions, if not addressed, could result in reduced structural integrity and consequent reduced controllability of the airplane.

(f) Compliance

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

(g) Revision of the (ALS) or ICA

Within 150 hours time-in-service (TIS) or 12 months after the effective date of this AD, whichever occurs first: Revise the Airworthiness Limitations Section (ALS) of the existing AMM or instructions for continued airworthiness (ICA) and the existing approved maintenance or inspection program, as applicable, by incorporating the revised tasks and associated thresholds and intervals identified in table 1 to paragraph (g) of this AD.

TABLE 1 TO PARAGRAPH (g)—REVISED MODEL 525B AIRWORTHINESS LIMITATION TASKS

Task No.	Task title	Existing task interval	Revised task interval	Inspection document	Zone
54–50–00–250 ...	Forward Engine Mount Channel Flange (Eddy Current) Special Detailed Inspection.	6,000 hours TIS	6,100 hours TIS, then 4,100 hours TIS thereafter.	4–12–NA	411, 412
54–50–00–252 ...	Aft Engine Beam Aft Upper Angle Common to Aft Web, BL 24.50 (Eddy Current) Special Detailed Inspection.	11,500 hours TIS	14,100 hours TIS, then every 2,700 hours TIS thereafter.	4–12–MR	311, 312
54–50–00–254 ...	Forward Engine Mount Aft Channel Web (Eddy Current) Special Detailed Inspection.	12,000 hours TIS	16,300 hours TIS, then every 11,600 hours TIS thereafter.	4–12–MS	410, 420
54–50–00–255 ...	Forward Engine Mount Forward Channel Web (Eddy Current) Special Detailed Inspection.	12,000 hours TIS	15,600 hours TIS, then every 11,100 hours TIS thereafter.	4–12–NB	410, 420
55–40–00–250 ...	Vertical Fin Left and Right Front Spar Cap at Attachment Hole #2 (Eddy Current) Special Detailed Inspection.	9,000 hours TIS, then every 7,500 hours TIS thereafter.	9,000 hours TIS, then every 7,000 hours TIS thereafter.	4–12–ML	340
55–40–00–251 ...	Vertical Fin Left and Right Front Spar Cap at Attachment Hole #1 (Eddy Current) Special Detailed Inspection.	15,000 hours TIS	17,700 hours TIS, then every 14,900 hours TIS thereafter.	4–12–MO	340

TABLE 1 TO PARAGRAPH (g)—REVISED MODEL 525B AIRWORTHINESS LIMITATION TASKS—Continued

Task No.	Task title	Existing task interval	Revised task interval	Inspection document	Zone
55–40–00–252 ...	Vertical Fin Left and Right Rear Spar Cap at Attachment Hole #1 (Eddy Current) Special Detailed Inspection.	15,000 hours TIS, then every 14,500 hours TIS thereafter.	23,600 hours TIS, then every 12,100 hours TIS thereafter.	4–12–MQ	340

Note 1 to paragraph (g): Additional guidance for accomplishing the actions required by this AD can be found in Textron Aviation Service Letter SL525B–05–04, Revision 1, dated January 7, 2025.

(h) Provisions for Alternative Actions and Intervals

After the action required by paragraph (g) of this AD has been done, no alternative actions and associated thresholds and intervals are allowed unless they are approved as specified in the provisions of paragraph (i) of this AD.

(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)(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 local flight standards district office/certificate holding district office.

(j) Additional Information

(1) For more information about this AD, contact Soban Saeed, Aviation Safety Engineer, FAA, 1801 South Airport Road, Wichita, KS 67209; phone: (316) 946–4123; email: CCB-COS@faa.gov.

(2) For Textron Aviation material identified in this AD that is not incorporated by reference, contact Textron Aviation, Inc., P.O. Box 7706, Wichita, KS 67277; phone: (316) 517–6215; email: citationpubs@txtav.com; website: ww2.txtav.com/technicalpublications/.

(k) Material Incorporated by Reference

None.

Issued on November 24, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–21416 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–5036; Project Identifier MCAI–2024–00748–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model EC120B helicopters. This proposed AD was prompted by a report of cyclic flight control restrictions due to the incorrect positioning of the bonding braid on the socket of the pilot cyclic stick, which limited full movement of the pilot cyclic stick during flight. This proposed AD would require a one-time inspection of the position of the bonding braid on the socket of the pilot cyclic stick and, depending on the results, correcting the positioning of the bonding braid and installing a binding clamp. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by January 12, 2026.

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

- *Federal eRulemaking Portal:* Go to regulations.gov. 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–2025–5036; or in person at Docket Operations between 9 a.m. and

5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

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

FOR FURTHER INFORMATION CONTACT:

Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–5225; email: steven.r.warwick@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–5036; Project Identifier MCAI–2024–00748–R” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

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

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2024–0243, dated December 13, 2024 (EASA AD 2024–0243) (also referred to as the MCAI), to address an unsafe condition for all Airbus Helicopters Model EC 120 B helicopters. The MCAI advises of a report that a pilot experienced several occurrences of a cyclic flight control restriction when turning right during an instruction flight. Subsequent investigation determined that the bonding braid on the socket of the pilot cyclic stick had moved to an incorrect position, which limited full movement

of the pilot cyclic stick. This condition, if not addressed, could result in a cyclic flight control restriction during flight and consequent loss of control of the helicopter.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–5036.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0243, which specifies a one-time inspection of the position of the bonding braid on the socket of the pilot cyclic stick and, depending on the results, correcting the positioning of the bonding braid and installing a binding clamp. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2024–0243, described previously, as incorporated by reference, except for any differences

identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some CAA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024–0243 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0243 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0243 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2024–0243. Material referenced in EASA AD 2024–0243 for compliance will be available at *regulations.gov* under Docket No. FAA–2025–5036 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 72 helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect position of bonding braid and install binding clamp.	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$6,120

The FAA estimates the following costs to do any repairs that would be

required based on the results of the proposed inspection. The agency has no

way of determining the number of helicopters that might need this repair.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Correct position of bonding braid	1 work-hour × \$85 per hour = \$85	\$0	\$85

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2025–5036; Project Identifier MCAI–2024–00748–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 12, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters EC120B helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 6700, Rotorcraft Flight Control.

(e) Unsafe Condition

This AD was prompted by a report of cyclic flight control restrictions due to the incorrect positioning of the bonding braid on the socket of the pilot cyclic stick, which limited full movement of the pilot cyclic stick during flight. The FAA is issuing this AD to detect and correct the incorrect positioning of the bonding braid on the socket of the pilot cyclic stick. The unsafe condition, if not addressed, could result in a cyclic flight control restriction during flight and consequent loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0243, dated December 13, 2024 (EASA AD 2024–0243).

(h) Exceptions to EASA AD 2024–0243

(1) Where EASA AD 2024–0243 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2024–0243 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(3) This AD does not adopt the "Remarks" section of EASA AD 2024–0243.

(i) Alternative Methods of Compliance (AMOCs)

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

identified in paragraph (j) of this AD and email to: AMOC@faa.gov.

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

(j) Additional Information

For more information about this AD, contact Steven Warwick, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–5225; email: steven.r.warwick@faa.gov.

(k) 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) European Union Aviation Safety Agency (EASA) AD 2024–0243, dated December 13, 2024.

(ii) [Reserved]

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

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

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

Issued on November 24, 2025.

Steven W. Thompson,

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

[FR Doc. 2025–21495 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 730

[Docket No. FDA–2023–N–4225]

RIN 0910–AI82

Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products; Withdrawal

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the withdrawal of the proposed rule entitled “Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products,” which published in the **Federal Register** of December 27, 2024. FDA is taking this action in response to comments received during the comment period for the proposed rule that warrant further consideration and assessment prior to issuing final regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products pursuant to the Modernization of Cosmetics Regulation Act of 2022.

DATES: The proposed rule published December 27, 2024 (89 FR 105490) is withdrawn as of November 28, 2025.

FOR FURTHER INFORMATION CONTACT: Elizabeth Anderson, Senior Policy Analyst, Food and Drug Administration, 240–402–4565, QuestionsAboutMoCRA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 27, 2024 (89 FR 105490), FDA issued the proposed rule entitled “Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products” as part of its implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which requires the promulgation of proposed and final regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products.

The proposed rule, if finalized, would require manufacturers of talc-containing cosmetic products to test their talc-containing cosmetic products or the talc cosmetic ingredient prior to using the talc to manufacture a talc-containing cosmetic for asbestos, and to keep records to demonstrate compliance with the rule. Failure to comply with the rule’s testing or recordkeeping obligations would result in FDA deeming a cosmetic product to be adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as would the presence of any asbestos in a talc-containing cosmetic product, talc used in a cosmetic product, or talc intended for use in a cosmetic. FDA received 49 comments on the proposed rule.

FDA proposed that the rule would apply to all manufacturers of talc-containing cosmetic products, including cosmetic products that are subject to the requirements of chapter V of the FD&C

Act (Drugs and Devices). Therefore, the proposed rule, if finalized, would apply to cosmetic products that are also drugs. FDA received comments that suggested the proposed rule would have unintended consequences for many consumer products containing talc, including but not limited to talc-containing cosmetic products.

FDA proposed to define “asbestos” to include “amosite, chrysotile, crocidolite; asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite; and other asbestiform amphibole minerals.” FDA received comments that requested consistency with the established definitions or approaches used by other Federal agencies, including the Department of Labor (Occupational Safety and Health Administration and Mine Safety and Health Administration) and Environmental Protection Agency, to avoid unnecessary confusion.

MoCRA requires FDA to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. The proposed rule was issued pursuant to MoCRA and sections 601 and 701 of the FD&C Act. FDA received comments regarding the Agency’s statutory authority under law to add a specific adulteration provision relating to talc testing and regarding its authority to consider a cosmetic containing any amount of asbestos to be adulterated.

Good cause exists to withdraw the proposed rule at this time. On the basis of the Make America Healthy Again (MAHA) priorities to ensure safe additives in the American food and drug supply, the highly scientific and technical issues addressed in public comments the Agency has received, and the complexity of asbestos testing and legal considerations under the Administrative Procedure Act, we are withdrawing the proposed rule to reconsider best means of addressing the issues covered by the proposed rule and broader principles to reduce exposure to asbestos, and to ensure that any standardized testing method requirements for detecting asbestos in talc-containing cosmetic products help protect users of talc-containing cosmetic products from harmful exposure to asbestos.

While the Agency is withdrawing the proposed rule, FDA will issue a proposed rule to meet its statutory

obligations under section 3505 of MoCRA.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.

[FR Doc. 2025–21407 Filed 11–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–124791–11]

RIN 1545–BK37

Furnishing Identifying Number of Tax Return Preparer

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: This document withdraws a notice of proposed rulemaking regarding the eligibility of tax return preparers to obtain a preparer tax identification number (PTIN). The proposed regulations would have affected tax return preparers.

DATES: As of November 28, 2025, the notice of proposed rulemaking that was published in the **Federal Register** on February 15, 2012 (77 FR 8753), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Mark Shurtliff at (202) 317–6845 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On February 15, 2012, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–124791–11) in the **Federal Register** (77 FR 8753) under section 6109 of the Internal Revenue Code (Code) relating to the identifying number of tax return preparers (proposed regulations). The proposed regulations would have provided for two additional categories of tax return preparers eligible for a PTIN under a regulatory scheme in which the IRS sought to impose minimum qualification requirements on who could be a tax return preparer.

Following publication of the proposed regulations, on February 11, 2014, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in *Loving v. Internal Revenue Service*, 742 F.3d 1013 (D.C. Cir. 2014), which upheld an injunction against the IRS from regulating tax return preparers.

In light of *Loving*, the IRS is prohibited from regulating tax return preparers and, therefore, the Treasury Department and the IRS are withdrawing the proposed regulations.

Drafting Information

The principal author of this notice is Mark Shurtliff of the Office of Associate Chief Counsel (Procedure and Administration). However, other personnel from the Treasury Department and the IRS participated in its development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Withdrawal of Proposed Amendments to the Regulations

Under the authority of 26 U.S.C. 7805, the notice of proposed rulemaking (REG-124791-11) that was published in the **Federal Register** on February 15, 2012 (77 FR 8753), is withdrawn.

Frank J. Bisignano,
Chief Executive Officer.

[FR Doc. 2025-21581 Filed 11-26-25; 8:45 am]

BILLING CODE 4830-GV-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA-R07-OAR-2025-2830; FRL-13059-01-R7]

Air Plan Approval; Missouri; Reporting Emission Data, Emission Fees, and Process Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of revisions to the Missouri State Implementation Plan (SIP), and Operating Permits Program related to Reporting Emission Data, Emission Fees, and Process Information. The revisions set emission fees and a base fee for calendar years 2025–2028 and beyond, add 1-Bromopropane to the category 1 Hazardous Air Pollutant list in table 1, update two publication dates for material that is incorporated by reference and make minor administrative changes to the rule. These revisions do not impact the stringency of the SIP or have an adverse effect on air quality. The EPA’s proposed approval of this rule revision is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: Comments must be received on or before December 29, 2025.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-R07-OAR-2025-2830 to <https://www.regulations.gov>. Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Written Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Steven Brown, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551-7718; email address: brown.steven@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document “we,” “us,” and “our” refer to the EPA.

Table of Contents

- I. Written Comments
- II. What is being addressed in this document?
- III. Have the requirements for approval of a SIP revision been met?
- IV. What action is the EPA taking?
- V. Incorporation by Reference
- VI. Statutory and Executive Order Reviews

I. Written Comments

Submit your comments, identified by Docket ID No. EPA-R07-OAR-2025-2830, at <https://www.regulations.gov>. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. What is being addressed in this document?

The EPA is proposing to approve revisions to the Missouri SIP and title V Operating Permits Program, 10–6.110 “Reporting Emission Data, Emission Fees, and Process Information,” submitted to the EPA on March 19, 2025. The amendments to this rule set emission fees and a base fee for calendar years 2025–2028 and beyond, add 1-Bromopropane to the category 1 Hazardous Air Pollutant list in table 1, update two publication dates for material that is incorporated by reference, and make minor administrative changes to the rule. The EPA proposes to find that these revisions meet the requirements of the CAA, do not impact the stringency of the SIP, and do not adversely impact air quality. The full text of the rule revisions can be found in the State submittal included in this docket.

III. Have the requirements for approval of a SIP revision been met?

The State submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision and related amendments to their Title V Operating Permits Program, from July 15, 2024, to September 5, 2024, and held a public hearing on August 29, 2024. The state of Missouri received one supporting comment during the public comment period on 10 CSR 10–6.110. The revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations and is consistent with applicable EPA requirements in title V of the CAA and 40 CFR part 70.

IV. What action is the EPA taking?

The EPA is proposing to amend the Missouri SIP by approving the State’s request to revise 10 CSR 10–6.110 “Reporting Emission Data, Emission Fees, and Process Information.” The EPA’s proposed action approves these amendments as part of the SIP, except for subsection (3)(A), which is not included in the SIP. However, the entire rule revision is being submitted for inclusion in the Missouri Title V program. These revisions update the emissions fee for permitted sources in subsection (3)(A) and the emission reporting years in table 4 of section (4)(B), as set by Missouri statute. Specifically, section (3)(A) revises the emission fees section, which is approved under the Operating Permits

Program only and is not being proposed to be approved in the Missouri SIP. The revised emission fees section updates the emissions fee for permitted sources as set by Missouri statute per ton of air pollution emitted annually for calendar years 2025–2028 and beyond and is effective January 1, 2026.

We are processing this as a proposed action because we are soliciting comments on this proposed action. Final rulemaking will occur after consideration of any comments.

V. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to finalize the incorporation by reference of the Missouri rule 10 CSR 10–6.110 discussed in section II. of this preamble and as set forth below in the proposed amendments to 40 CFR part 52. The purpose of this state regulation is to provide procedures for reporting emission related information and establishing emission fees for the purpose of state air resource planning. The EPA has made, and will continue to make, these materials generally available through <https://www.regulations.gov> and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action

merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
 - Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because State Implementation Plan actions are exempt from review under Executive Order 12866;
 - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
 - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
 - Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
 - Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
 - Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
 - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
 - Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.
- In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have

Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects

40 CFR Part 52

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

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: November 17, 2025.

James Macy,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR parts 52 and 70 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart AA—Missouri

- 2. In § 52.1320, the table in paragraph (c) is amended by revising the entry “10–6.110” to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
*	*	*	*	*

EPA-APPROVED MISSOURI REGULATIONS—Continued

Missouri citation	Title	State effective date	EPA approval date	Explanation
10–6.110	Reporting Emission Data, Emission Fees, and Process Information.	1/1/2026	[Date of publication of the final rule in the Federal Register], 90 FR [Federal Register page where the document begins of the final rule].	Subsection (3)(A) is not being approved in the SIP.
*	*	*	*	*

* * * * *

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 3. The authority citation for part 70 continues to read as follows:

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

■ 4. Appendix A to part 70 is amended by adding paragraph (kk) under “Missouri” to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Missouri

* * * * *

(kk) The Missouri Department of Natural Resources submitted revisions to Missouri rule 10 CSR 10–6.110, “Reporting Emission Data, Emission Fees, and Process Information” on March 19, 2025. The state effective date is January 1, 2026. This revision is effective [date 60 days after date of publication of the final rule in the **Federal Register**].

* * * * *

[FR Doc. 2025–21346 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2025–0226; FRL–13007–01–R3]

Air Plan Approval; Virginia; Repeal of Existing Stationary Source Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision (Revision B23) submitted by the Commonwealth of Virginia. The revision seeks to remove two existing stationary sources regulations, emission standards for petroleum refinery operations and emissions standards for

large appliance coating application systems, from Virginia’s SIP as there are no longer any applicable sources in Virginia. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before December 29, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2025–0226 at www.regulations.gov, or via email to gordon.mike@epa.gov. For comments submitted at Regulations.gov, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit www.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: Sarah McCabe, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1600 John F Kennedy Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–5786. Ms. McCabe can also be reached via electronic mail at mccabe.sarah@epa.gov.

SUPPLEMENTARY INFORMATION: On December 20, 2024, the Virginia Department of Environmental Quality (VADEQ) submitted Revision B23 to its SIP. The revision seeks to repeal Article 11, Emission Standards for Petroleum Refinery Operations (9VAC5–40–1340 through 5–40–1510), and Article 26, Emissions Standards for Large Appliance Coating Application Systems (9VAC5–40–3560 through 5–40–3700) from existing stationary source regulations in the Virginia SIP, as there are no longer any facilities within the state subject to the regulations. Virginia has already repealed the regulations from the Virginia Administrative Code (VAC).

I. Background

The CAA mandates that the EPA set national ambient air quality standards (NAAQS) for criteria pollutants, which are ozone and related photochemical oxidants, carbon monoxide, lead, nitrogen oxides, particulate matter, and sulfur oxides. The CAA also requires the EPA to periodically review the relevant scientific information and the standards and revise them, if appropriate, to ensure that the standards provide the requisite protection for public health and the environment. The CAA requires states to develop a general plan to attain and maintain the standards in all areas of the country and a specific plan to attain the standards for each area designated nonattainment.

In 1972, Virginia promulgated standards on emissions from Existing Stationary Sources (9VAC5–40). The articles pertaining to this rulemaking, Articles 11 and 26, establish regulations regarding petroleum refineries and large appliance coating application systems, respectively. Article 11 was promulgated in 1972 to control emissions of criteria pollutants, such as particulate matter, sulfur dioxide, and volatile organic compounds (VOCs) as well as hydrogen sulfide. Article 26 was also promulgated in 1972 to control emissions of VOCs. The EPA adopted Article 11 and Article 26 into Virginia’s SIP on April 21, 2000 (65 FR 21315).

Virginia state agencies are required to review regulations periodically in order to determine whether they are still needed. A public review of 9VAC5–40, including a review of the VADEQ's Comprehensive Environmental Data System database, demonstrated that there are no longer any facilities within the state subject to Article 11, Emission Standards for Petroleum Refinery Operations, or Article 26, Emissions Standards for Large Appliance Coating Application Systems.

II. Summary of SIP Revision and EPA Analysis

On December 20, 2024, VADEQ submitted a SIP revision (Revision B23) consisting of amendments to Virginia's regulations regarding existing stationary sources (9VAC5–40). The revision proposes to repeal Article 11, Emission Standards for Petroleum Refinery Operations (9VAC5–40–1340 through 5–40–1510), and Article 26, Emissions Standards for Large Appliance Coating Application Systems (9VAC5–40–3560 through 5–40–3700), from the Virginia SIP because there are no remaining petroleum refinery operations or large appliance coating application systems in Virginia. Additionally, any future such facilities constructed in Virginia would be subject to more stringent Federal and State regulations, such as New Source Review, than Articles 11 and 26 in 9VAC5–40.

Section 110(l) of the CAA indicates that the EPA cannot approve a SIP revision if the revision interferes with reasonable further progress (RFP), any NAAQS, or any other CAA requirement. Therefore, the EPA will approve a SIP revision that removes or modifies measures only after the state has demonstrated noninterference with RFP, the NAAQS, or any other CAA requirement. Virginia demonstrated noninterference through a review of 9VAC5–40 and VADEQ's Comprehensive Environmental Data System database, indicating that there are no longer any facilities subject to the articles proposed for removal. Additionally, the EPA confirmed that there are neither petroleum refineries nor large appliance coating application systems remaining in Virginia through the analysis of the most recently available emissions data.¹ CAA section 110(l) also states that a revision to an implementation plan submitted by a state shall be adopted by such state after reasonable notice and public hearing. Revision B23 meets such public notice and public hearing requirements through Virginia's certification of public

participation activities and compliance with state administrative procedures document, which can be found in the docket of this rulemaking.

The removal of Articles 11 and 26 in 9VAC5–40 has no expected emissions impact on any pollutant because there are no existing affected facilities in Virginia and the removal of the regulations is not expected to interfere with reasonable further progress, any NAAQS, or any other CAA requirement. Therefore, the removal of Articles 11 and 26 in 9VAC5–40 from the Virginia SIP is in accordance with section 110(l) of the CAA.

The regulations were repealed by Virginia's State Air Pollution Control Board on September 13, 2023. As the regulations have been repealed, they may be removed from Virginia's SIP.

III. Proposed Action

The EPA is proposing to approve Revision B23, submitted on December 20, 2024 by VADEQ, as a revision to the Virginia SIP, because the submission meets the requirements of CAA section 110. Revision B23 repeals Article 11, Emission Standards for Petroleum Refinery Operations (9VAC5–40–1340 through 5–40–1510), and Article 26, Emissions Standards for Large Appliance Coating Application Systems (9VAC5–40–3560 through 5–40–3700) from the Virginia SIP. The EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) “privilege” for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the

content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information “required by law,” including documents and information “required by Federal law to maintain program delegation, authorization or approval,” since Virginia must “enforce federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. . . .” The opinion concludes that “[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.”

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that “[t]o the extent consistent with requirements imposed by Federal law,” any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any federally authorized programs, since “no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.”

Therefore, the EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because the EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, the EPA may at any time invoke its authority under the

¹ 2020 National Emissions Inventory (NEI).

CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

V. Incorporation by Reference

In this document, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference amendments to Virginia Administrative Code 9VAC5–40 Existing Stationary Sources, repealing 9VAC5–40–1340 through 9VAC5–40–1510, and 9VAC5–40–3560 through 9VAC5–40–3700, as described in section II of this document. The EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely

affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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

List of Subjects in 40 CFR Part 52

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

Amy Van Blarcom-Lackey,

Regional Administrator, Region III.

[FR Doc. 2025–21557 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2025–0653; FRL–13092–01–R1]

Air Plan Approval; Connecticut; New Source Review Permit Program State Plan Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Connecticut. This action consists of revisions to Connecticut's New Source Review (NSR) permit program, primarily to clarify applicability for stationary sources in nonattainment

areas. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before December 29, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2025–0653 at <https://www.regulations.gov>, or via email to turner.andre@epa.gov. For comments submitted at Regulations.gov, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that, if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection.

FOR FURTHER INFORMATION CONTACT: Andre Turner, U.S. Environmental Protection Agency, Region 1 Office of Air and Radiation Division, 5 Post Office Square, Suite 100, Boston, MA 02109, Phone number: (617) 918–1216, Email: turner.andre@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

Table of Contents

- I. Background
- II. Description and Review of Submittal
- III. EPA's Evaluation of CT DEEP's Submittal
 1. RCSA Section 22a–174–3a(a)(2)(C)(ii)

- 2. RCSA Section 22a–174–3a(l)(1)(B)
- 3. RCSA Section 22a–174–3a(l)(1)(C)
- IV. Proposed Action
- V. Incorporation by Reference
- VI. Statutory and Executive Order Reviews

I. Background

The Connecticut Department of Energy and Environmental Protection (CT DEEP) established its SIP, including its NSR permit program, in 1972 in accordance with CAA section 110 and 40 CFR part 51. Since then, there have been numerous revisions to the SIP in accordance with state and federal air permitting regulations. The most recent federally enforceable revision to Connecticut's NSR permit program was approved into the SIP by EPA on September 5, 2023, and included changes to sections 22a–174–2a and 22a–174–3a of the Regulations of Connecticut State Agencies (RCSA).

II. Description and Review of Submittal

On October 3, 2024,¹ CT DEEP submitted a SIP revision containing changes to RCSA section 22a–174–3a, primarily to clarify the applicability of Connecticut's permit requirements for stationary sources in nonattainment areas. These revisions to RCSA became effective, as a matter of state enforceability, on March 14, 2024.

The first revision made by CT DEEP is to RCSA section 22a–174–3a(a)(2)(C)(ii), which references the federal definition of a “non-road engine.” The citation to 40 CFR part 89 in this clause was amended to 40 CFR 1068.30 in order to reflect the correct citation after EPA renumbering. The two other revisions relate to subsection (l) of RCSA section 22a–174–3a, which addresses permit requirements for nonattainment areas. Subparagraph (B) of subdivision (1) of subsection (l) is amended to clarify how the subsection applies to modifications. The revised text provides more detail on how changes to an existing unit may be considered a major modification. The amended text also includes references to Table 3a(k)–1, which lists the significant emission rate threshold values for pollutants and their precursors. In subparagraph (C) of the same subdivision, the text is revised to add the phrase “for such pollutant” after “nonattainment area” for clarity.

III. EPA's Evaluation of CT DEEP's Submittal

EPA has reviewed the following revisions to RCSA section 22a–174–3a submitted by CT DEEP.

1. RCSA Section 22a–174–3a(a)(2)(C)(ii)

CT DEEP revised this provision to replace the outdated reference to 40 CFR part 89 with the current federal definition of “nonroad engine” at 40 CFR 1068.30. EPA has determined that this correction does not change the applicability of the exemption for nonroad engines but ensures that the state regulation references the appropriate federal definition.

2. RCSA Section 22a–174–3a(l)(1)(B)

CT DEEP revised this provision to clarify the applicability of nonattainment new source review (NNSR) requirements to modifications at major stationary sources. The revised regulations clarify that the NNSR program applies to two categories of modifications:

- (i) modifications to an emission unit that is itself a major stationary source that triggers NNSR when the modification results in a significant emissions increase equal to or greater than the significant emission rate thresholds of a pollutant (or their precursors) for which the area is designated as nonattainment; or
- (ii) modifications to a premises that is a major stationary source that triggers NNSR when the modification results in a net emissions increase equal to or greater than the significant emission rate threshold of a pollutant (or their precursors) for which the area is designated as nonattainment.

The revisions to 22a–174–3a(l)(1)(B) do not change NNSR applicability thresholds, offset obligations, or control technology requirements, but rather clarify the circumstances that a modification may be considered major and trigger NNSR to either a unit itself or to a premises that is considered a major stationary source. EPA has determined that this revision appropriately clarifies NNSR applicability for major modifications and is consistent with EPA's 40 CFR 51.165 requirements for state NNSR programs.

3. RCSA Section 22a–174–3a(l)(1)(C)

CT DEEP revised this provision by adding the phrase “for such pollutant” after “nonattainment area.” This revision clarifies that NNSR requirements apply only to nonattainment pollutants (and their precursors) at new major stationary sources and modifications at existing

major stationary sources located in nonattainment areas. The revisions to 22a–174–3a(l)(1)(C) do not change NNSR applicability thresholds, offset obligations, or control technology requirements. EPA has determined that this revision clarifies NNSR applicability and is consistent with EPA's 40 CFR 51.165 requirements for state NNSR programs.

IV. Proposed Action

EPA is proposing to approve Connecticut's October 3, 2024, SIP submittal that addresses revisions to RCSA section 22a–174–3a. EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

V. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the changes to RCSA section 22a–174–3a as adopted on March 14, 2024, and discussed in Section II of this preamble. The EPA has made, and will continue to make, these documents generally available through <https://www.regulations.gov> and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under

¹ The Connecticut SIP cover letter lists a submittal date of June 27, 2024, however EPA received this through the online submittal system State Planning Electronic Collaboration System (SPECS) on October 3, 2024.

Executive Orders 12866 (58 FR 51735, October 4, 1993);

- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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

List of Subjects in 40 CFR Part 52

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

Dated: November 20, 2025.

Mark Sanborn,

Regional Administrator, EPA Region 1.

[FR Doc. 2025–21413 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA–HQ–OLEM–2025–2864; FRL–12968–01–OLEM]

RIN 2050–AH42

Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Extension of an Alternative Closure Requirement Deadline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of public hearing.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to extend, by three years, one compliance deadline applicable to certain coal combustion residuals (CCR) surface impoundments operating pursuant to the alternative closure requirements. Specifically, EPA is extending the deadline for owners and operators to complete closure of their unlined CCR surface impoundments larger than 40 acres from October 17, 2028, to October 17, 2031. This deadline extension will promote electric grid reliability by allowing a subset of coal-fired power producers to continue to operate beyond their currently scheduled retirement date.

DATES: Comments must be received on or before January 7, 2026. *Public Hearing.* EPA will hold a virtual public hearing on January 6, 2026. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2025–2864, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Land and Emergency Management (OLEM) Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking (*i.e.*, EPA–HQ–OLEM–

2025–2864). Comments received may be posted without change to <https://www.regulations.gov>, including personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may be found at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Patrick Wise, Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, MC: 5304T, Washington, DC 20460; telephone number: (202) 566–0520; email address: Wise.Patrick@epa.gov; or Frank Behan, Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, MC: 5304T, Washington, DC 20460; telephone number: (202) 566–0531; email address: Behan.Frank@epa.gov. For more information on this rulemaking please visit <https://www.epa.gov/coal-combustion-residuals>.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Public Participation
- II. General Information
- III. Background
- IV. Revised Deadline for Cessation of Operations and Unit Closure
- V. The Projected Economic Impact of This Action
- VI. Statutory and Executive Order Reviews

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2025–2864, at <https://www.regulations.gov> (our preferred method), or the other methods identified in the **ADDRESSES** section. 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). Please visit <https://www.epa.gov/dockets/commenting-epa-dockets> for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

B. Notice of Public Hearing

EPA is providing the minimum required 30-days' notice of this public hearing. EPA evaluated the complexity and technical nature of this proposed rule. The scope of this action is limited to extending one compliance deadline applicable to certain CCR surface impoundments operating pursuant to the alternative closure requirements. EPA determined this issue is not complex or highly technical and therefore 30 days' notice of the public hearing for this proposed rule was adequate to provide the public with meaningful opportunity to comment on the regulatory change.

C. Public Hearing

EPA will hold a virtual public hearing on January 6, 2026. The hearing will convene at 9:00 a.m. Eastern Time (ET) and conclude at 1:00 p.m. (ET).

EPA will begin pre-registering speakers for the virtual public hearing upon publication of this document in the **Federal Register**. To register to speak at the hearing, please use the online registration form available on EPA's CCR website <https://www.epa.gov/coal-combustion-residuals> or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to register to speak at the hearing. Both virtual hearing speakers and attendees are requested to pre-register at the link provided above. The last day to pre-register to speak at the hearing will be January 2, 2026.

EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule. Additionally, requests to speak will be taken the day of the hearing via the Q&A functionality of the online platform. EPA will make every effort to accommodate all speakers who wish to provide oral testimony, although preferences on speaking times may not be able to be fulfilled.

Each commenter will have five (5) minutes to provide oral testimony. EPA encourages commenters to provide EPA

with a copy of their oral testimony electronically by emailing it to the person listed in the **FOR FURTHER INFORMATION CONTACT** section. EPA also recommends submitting the text of your oral comments as written comments to the rulemaking docket. If EPA is anticipating a high attendance, the time allotment per testimony may be shortened to no shorter than three (3) minutes per person to accommodate all those wishing to provide testimony and who have pre-registered. While EPA will make every effort to accommodate all speakers who do not preregister, opportunities to speak may be limited based upon the number of pre-registered speakers. Therefore, EPA strongly encourages anyone wishing to speak to preregister. Participation in the public hearing does not preclude any entity or individual from submitting a written comment.

EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing are posted online at EPA's CCR website at <https://www.epa.gov/coal-combustion-residuals>. While EPA expects the hearing to go forward as set forth above, please monitor our website or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to determine if there are any updates. EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of an interpreter or special accommodations such as audio transcription or closed captioning, please pre-register for the hearing and describe your needs on the registration form by December 17, 2025. Alternatively, registrants may notify the person listed in the **FOR FURTHER INFORMATION CONTACT** section of any special needs. EPA may not be able to arrange accommodations without advance notice.

II. General Information

A. Does this action apply to me?

This proposed rule may be of interest to electric utilities and independent power producers that fall within the North American Industry Classification System (NAICS) code 221112 and that submitted a complete demonstration pursuant to section 257.103(f)(2). The following eleven power plants are

currently operating unlined CCR surface impoundments larger than 40 acres under a pending demonstration: Baldwin Power Station (IL), Big Cajun II Power Plant (LA), Brame Energy Center (LA), Coletto Creek Power Plant (TX), Intermountain Generating Facility (UT), Kincaid Power Station (IL), Miami Fort Power Station (OH), Naughton Power Plant (WY), Newton Power Station (IL), R.M. Schahfer Generating Station (IN), and Welsh Power Plant (TX). To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in section 257.50 of title 40 of the Code of Federal Regulations (CFR).¹ If you have questions regarding the applicability of this action to a particular entity, consult the persons listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the Agency taking?

This proposed rule extends one compliance deadline applicable to certain impoundments currently operating pursuant to the alternative closure requirements under section 257.103(f)(2). Specifically, EPA is extending the existing deadline for owners and operators to complete closure of their unlined CCR surface impoundments larger than 40 acres from October 17, 2028, to October 17, 2031. See section 257.103(f)(2)(iv)(B). This deadline extension will promote electric grid reliability by allowing the coal-fired steam generating units at these facilities to continue to operate beyond their currently scheduled retirement dates.

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

EPA is publishing this rulemaking under the authority of sections 1008(a)(3), 2002(a), 4004, and 4005(a), (d) of the Solid Waste Disposal Act of 1965, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 and the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, 42 U.S.C. 6907(a), 6912(a), 6944, 6945(a) and (d).

D. What are the incremental costs and benefits of this proposed rule?

EPA establishes the requirements under RCRA sections 1008(a)(3) and 4004(a) without taking cost into account. *See Utility Solid Waste Activities Group, et al. v. EPA (USWAG)* 901 F.3d 414, 448–49 (D.C. Cir. 2018). The following cost estimates are

¹ Unless otherwise stated, all citations specified in this action are found in title 40 of the CFR.

presented in the Regulatory Impact Analysis (RIA) and summarized in this preamble for compliance with E.O. 12866 and consistent with OMB Circular A-4.

The RIA estimates that the annualized cost savings of this proposed rule will be approximately \$7–12 million per year when discounting at 3%. The RIA estimates that the annualized cost savings of this action will be approximately \$17–27 million per year when discounting at 7%. Further information on the economic effects of this action can be found in Unit V of this preamble. EPA also qualitatively considered the grid reliability and air emissions impacts of this proposed rule. Further details can be found in section V of the preamble.

III. Background

A. Summary of the Alternative Closure Requirements Under Section 257.103(f)

In April 2015, EPA issued its first set of regulations establishing requirements for CCR surface impoundments and landfills. “Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals From Electric Utilities,” (2015 CCR Rule) 80 FR 21302 (Apr. 17, 2015). These requirements included criteria consisting of location restrictions, design and operating criteria, groundwater monitoring and corrective action requirements, closure and post-closure care requirements, recordkeeping, notification, and internet posting requirements. The closure criteria included alternative closure provisions under section 257.103. See 80 FR 21423–24.

In August 2020, EPA issued revisions to that rule, including revisions to the alternative closure requirements. “Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals From Electric Utilities; A Holistic Approach to Closure Part A: Deadline to Initiate Closure rule,” 85 FR 53516 (Aug. 28, 2020) (the “Part A Rule”). The Part A Rule established April 11, 2021, as the date that electric utilities must cease placing waste into all unlined CCR surface impoundments. The Part A Rule also revised the alternative closure provisions of the CCR regulations (section 257.103) by allowing owners or operators to request an extension to continue to receive CCR and/or non-CCR waste streams in unlined CCR surface impoundments after April 11, 2021, provided that certain criteria are met. EPA established two site-specific alternatives to initiate closure of unlined CCR surface impoundments (section 257.103(f)), commonly known

as extensions of the date to cease receipt of waste.

The first alternative is for a facility that must continue to use an unlined CCR surface impoundment after April 11, 2021, because no alternative disposal capacity is available either on-site or off-site, and it was technically infeasible to develop alternative capacity by that date. Section 257.103(f)(1) (titled *Development of Alternative Capacity is Technically Infeasible*). The second alternative is for coal-fired boiler(s) that are going to permanently shut down by a date certain after April 11, 2021, but there is no alternative capacity either on- or off-site that is available to accept the CCR and non-CCR waste streams between April 11, 2021, and the permanent closure date of the coal-fired boiler. Section 257.103(f)(2) (titled *Permanent Cessation of Coal-Fired Boiler(s) by a Date Certain*). This proposed rule only pertains to the second alternative because facilities operating under the first alternative have all already obtained alternative disposal capacity, thus allowing continued use of associated coal-fired boilers. Section 257.103(f)(2) establishes deadlines for when the facility must both cease operation of its coal-fired boiler and complete closure of the unlined surface impoundment. The existing deadlines are based on the size of the impoundment, using surface area as a surrogate for impoundment size. For impoundments that are 40 acres or smaller, owners and operators were required to cease operation of the coal-fired boiler and complete closure of the impoundment no later than October 17, 2023. For impoundments that are larger than 40 acres, the deadline is October 17, 2028. See section 257.103(f)(2)(iv).

As provided in section 257.103(f)(3)(i), November 30, 2020, was the deadline for facilities to submit requests to EPA to operate an unlined impoundment beyond April 11, 2021, pursuant to section 257.103(f)(2). As discussed in Unit IV of this preamble, this action is not revising the November 30, 2020, deadline to allow additional owners and operators to submit new time extension requests. EPA received 23 complete extension requests under section 257.103(f)(2) before the November 30, 2020, deadline, including seven facility requests with impoundments that are 40 acres or smaller and 16 facility requests with impoundments larger than 40 acres.² Of the 16 extension requests with impoundments larger than 40 acres, 11

facilities are currently operating these impoundments pursuant to section 257.103(f)(2). EPA has not yet taken action to determine whether to grant these 11 extension requests.

B. Facilities Currently Operating Impoundments Under Section 257.103(f)(2)

Eleven power plants are currently operating at least one unlined CCR surface impoundment under a pending extension request submitted pursuant to section 257.103(f)(2). EPA below summarizes information about these impoundments and the coal-fired steam generating units that rely on the continued operation of the unlined impoundments (*i.e.*, CCR or non-CCR waste streams from the boilers units are being routed to the impoundment). The summaries are based on information presented in the November 2020 Demonstrations³ and the most recent annual progress report required by section 257.103(f)(2)(x), if the progress report provides new relevant information.⁴ The summaries below are organized by the electric power market in which the facility falls. Five of these facilities fall within the electric power market operated by the Midcontinent Independent System Operator, two within PJM Interconnection, and one facility each in Electric Reliability Council of Texas, Northwest, Southwest, and Southwest Power Pool.

1. Midcontinent Independent System Operator (MISO)

- **Baldwin Power Station (Baldwin)** located in Illinois. According to the 2020 Demonstration submitted by Dynegy Midwest Generation LLC (Dynegy), Baldwin is a 1,185 megawatt (MW) coal-fired electric generating station located near Baldwin, Illinois. The unlined CCR surface impoundment operating pursuant to the extension request is the Bottom Ash Pond. The time frames discussed in the 2020 Demonstration stated that the two coal-fired boilers (Units 1 and 2) would cease operations no later than December 31, 2025. Furthermore, Baldwin anticipated that all CCR and non-CCR waste streams going to the Bottom Ash Pond would cease by July 17, 2027, and closure of

³ Demonstrations supporting the extension requests can be accessed on each facility's publicly accessible CCR website. EPA's website includes a list of publicly accessible internet sites at <https://www.epa.gov/coal-combustion-residuals>.

⁴ The annual progress report documents the continued lack of alternative disposal capacity and the progress towards the closure of the CCR surface impoundment(s) covered by the extension request.

² EPA issued letters of completeness on January 11, 2022.

the impoundment would be completed by October 17, 2028. On April 2, 2025, Dynegy submitted an update to the closure schedule and closure plan (Baldwin Update) associated with its 2020 Demonstration. In the Baldwin Update, Dynegy stated that Units 1 and 2 will continue to operate for up to an additional two years to no later than December 31, 2027, due to “recent reliability and market conditions in MISO.”⁵ Dynegy further stated in this update that closure of the Bottom Ash Pond would still be completed by October 17, 2028 (same as stated in 2020 Demonstration) because closure has already begun and is being conducted in two phases starting in 2025.

- *Big Cajun II Power Plant (Big Cajun II) located in Louisiana.* In November 2020, Cleco Cajun LLC (Cleco) submitted an extension request for the unlined Bottom Ash Basin located near New Roads, Louisiana. According to the 2020 Demonstration, the Bottom Ash Basin receives CCR (bottom ash) from Unit 1, which is a 580 MW coal-fired steam generating unit. The Bottom Ash Basin also receives other non-CCR waste streams (*i.e.*, clarifier/softener underflow) from Unit 1, as well as from Unit 2 (a natural gas unit) and Unit 3 (a coal-fueled unit).⁶ Cleco stated in its 2020 Demonstration that the Unit 1 boiler is subject to a 2013 consent decree requiring that Unit 1 “cease generation of coal-fired energy by no later than April 1, 2025.” Furthermore, Big Cajun II anticipated that all waste streams going to the Bottom Ash Basin would cease by approximately March or April 2027, and closure of the impoundment will be completed by October 17, 2028. Given the existence of the consent decree, EPA believes that this rule would not allow Unit 1 to generate electricity beyond April 1, 2025; however, this action would allow the Bottom Ash Basin to be closed over a longer period should Big Cajun II need additional time.

- *Brame Energy Center (Brame) located in Louisiana.* According to the 2020 Demonstration submitted by Cleco Power LLC, Brame operates a 523 MW coal-fired steam generating unit called Rodemacher Unit 2. Brame is located in Lena, Louisiana. The unlined CCR surface impoundment operating

pursuant to the extension request is the Bottom Ash Pond, which receives CCR waste streams related to Rodemacher Unit 2. The time frames discussed in the 2020 Demonstration stated that closure of the Bottom Ash Pond will be completed by no later than October 17, 2028. To meet this deadline, Cleco Power stated it plans to cease operation of Rodemacher Unit 2 by no later than August or September 2027. Brame also operates steam generating units fueled by natural gas (Unit 1) and petroleum coke (Unit 3); however, waste streams from those generating units are not disposed in the Bottom Ash Pond and therefore are not impacted by this rulemaking.

- *Newton Power Station (Newton) located in Illinois.* In November 2020, Illinois Power Generating Company (IPGC) submitted an extension request for the unlined Primary Ash Pond located near Newton, Illinois. According to the 2020 Demonstration, Newton is a 615 MW steam electric generating facility with one coal-fired boiler. The Primary Ash Pond receives various CCR and non-CCR waste streams. IPGC further stated that it is scheduled to cease coal-fired boiler operation no later than July 17, 2027. On October 22, 2025, IPGC submitted an update to the closure schedule and closure plan (Newton Update) associated with its 2020 Demonstration. In the Newton Update, IPGC stated that Unit 1 will continue to operate for an additional six weeks to no later than September 1, 2027, due to “recent reliability and market conditions in MISO.”⁷ Furthermore, the schedule shows placement of all waste streams into Primary Ash Pond will cease by December, 2027, so that closure of the Primary Ash Pond will be completed by October 17, 2028.

- *R.M. Schahfer Generating Station (RM Schahfer) located in Indiana.* At the time Northern Indiana Public Service Company (NIPSCO) submitted the 2020 Demonstration for the Waste Disposal Area, RM Schahfer operated four coal-fired boilers. The Waste Disposal Area is an unlined CCR surface impoundment that receives CCR and non-CCR waste streams associated with these boilers. By October 2021, NIPSCO permanently retired two of the four coal-fired boilers and planned to retire the remaining two coal-fired boilers in 2023.⁸ As further explained in the 2025

Annual Update,⁹ following communications with MISO in 2022, “NIPSCO identified the need to extend coal-fired generation at [RM Schahfer] beyond the originally planned 2023 retirement date.” Currently, these two coal-fired boilers are scheduled to cease coal-fired generation by December 31, 2025. Furthermore, the current schedule shows placement of all waste streams into the Waste Disposal Area by no later than September 2026, so that closure of the impoundment will be completed by October 17, 2028. The two operating coal-fired boilers have a combined generating capacity of 847 MW. NIPSCO has stated that RM Schahfer would operate its coal-fired boilers until 2028 if the proposed rule change was finalized.

2. PJM Interconnection (PJM)

- *Kincaid Power Station (Kincaid) located in Illinois.* In November 2020, Kincaid Generation, LLC submitted an extension request for the unlined Ash Pond located near Kincaid, Illinois. According to the 2020 Demonstration, Kincaid is a 1,108 MW steam electric generating facility with two coal-fired boilers. The Ash Pond receives various CCR and non-CCR waste streams associated with the two generating units. Kincaid Generation stated that the two coal-fired boilers will be retired no later than July 17, 2027. Furthermore, the schedule shows placement of all waste streams into Ash Pond will cease by September 17, 2027, so that closure of the Ash Pond can be completed by October 17, 2028.

- *Miami Fort Power Station (Miami Fort) located in Ohio.* Dynegy Miami Fort, LLC (Dynegy) stated in its 2020 Demonstration that Miami Fort is a 1,100 MW two unit (Units 7 and 8), coal-fired steam electric generating station located near North Bend, Ohio. The Miami Fort Pond System is the unlined impoundment operating pursuant to the extension request and receives CCR waste streams (bottom ash and fly ash), as well as other non-CCR waste streams. The time frames discussed in the 2020 Demonstration stated that closure of the Miami Fort Pond System will be completed by no later than October 17, 2028. To meet this deadline, Dynegy plans to cease operation of boiler Units 7 and 8 by no later than June 17, 2027, and cease placement of wastes into the impoundment by August 17, 2027.

⁵ Dynegy Midwest Generation LLC, “Baldwin Power Station Alternative Closure Demonstration—Update to Schedule and Closure Plan,” April 2, 2025. See also Attachment 2 that includes “Comments from the Midcontinent Independent System Operator, Inc. regarding the Baldwin Energy Station adjusted retirement date and the need to maintain existing generation for reliability” dated December 18, 2024.

⁶ CCR waste streams (bottom ash) from Unit 3 is dry handled and taken off-site.

⁷ Illinois Power Generating Company, “Newton Power Plant Alternative Closure Demonstration—Update to Schedule and Closure Plan,” October 22, 2025.

⁸ WSP USW Inc. “Northern Indiana Public Service Company LLC, R.M. Schahfer Generating Station Wheatfield, Indiana, CCR Surface Impoundment No Alternative Disposal Capacity

Documentation—2025 Annual Update Pursuant to Indiana Administrative Code 329 IAC 10–9–1,” Feb. 5, 2025.

⁹ Id. at 2.

3. Electric Reliability Council of Texas (ERCOT)

- *Coletto Creek Power Plant (Coletto Creek) located in Texas.* In November 2020, Coletto Creek Power, LLC submitted an extension request for the unlined Coletto Creek Primary Ash Pond located near Fannin, Texas. According to the 2020 Demonstration, the Primary Ash Pond receives CCR (bottom ash, economizer ash and mill rejects) and various non-CCR waste streams associated with the 650 MW coal-fired steam generating unit. Coletto Creek Power stated that the boiler will cease coal-fired operations no later than July 17, 2027. Furthermore, Coletto Creek anticipates that it will cease placing all waste streams into Primary Ash Pond by September 17, 2027, so that closure of the Primary Ash Pond can be completed by October 17, 2028. In its most recent annual progress report, Coletto Creek Power noted plans to convert the plant to operate on natural gas after coal-firing operations cease in 2027.¹⁰

4. Southwest Power Pool (SPP)

- *J. Robert Welsh Power Plant (Welsh Plant) located in Texas.* In November 2020, Southwestern Electric Power Company (SWEPCO) submitted an extension request for the Primary Bottom Ash Pond at the Welsh Plant to allow the unlined impoundment to continue to receive CCR and non-CCR waste streams. The Welsh Plant is a 1,056 MW coal-fired steam electric generating station located in Pittsburgh, Texas. The time frames discussed in the 2020 Demonstration stated that closure of the Primary Bottom Ash Pond will be completed in two phases with the first phase of closure construction beginning in February 2027. The second phase of closure construction is planned to commence in March 2028 and to coincide with the cessation of coal-fired boiler operations. Closure of the Primary Bottom Ash Pond would be completed by no later than October 17, 2028.

5. Southwest

- *Intermountain Generating Facility (Intermountain) located in Utah.* Intermountain Power Service Corporation (IPSC) stated in its 2020 Demonstration that Intermountain is a 1,900 MW coal-fired steam electric generating station located near Delta, Utah. The unlined CCR surface impoundments operating pursuant to the extension request are the Bottom Ash Basin and Waste Water Basin, both of which receive CCR waste streams

related to the coal-fired boiler units. The time frames presented in the 2020 Demonstration state that closure of both unlined impoundments will be completed by no later than October 17, 2028. IPSC plans to cease operation of both coal-fired boilers by July 1, 2025, explaining that such plans were first announced in May 2017. IPSC further explains it is already “moving forward with plans to develop new natural gas and hydrogen-fueled electricity generation” at Intermountain. These plans were confirmed in the most recent annual progress report.¹¹

6. Northwest

- *Naughton Power Plant located in Wyoming.* In November 2020, PacifiCorp submitted an extension request for the South Ash Pond at Naughton to receive bottom ash and fly ash. Non-CCR waste streams are no longer routed to the South Ash Pond. Two coal-fired boilers at Naughton provide approximately 380 MW of generating capacity. PacifiCorp states that the two coal-fired boilers will cease operation on December 31, 2025. The time frames discussed in the 2020 Demonstration show that placement of CCR waste streams will permanently cease by September 30, 2026, in order to complete closure by the regulatory deadline. PacifiCorp states in its most recent annual progress report that Naughton is on schedule to cease operating the coal-fired boilers by the end of 2025.

C. Resource Adequacy Reports Issued by NERC and U.S. DOE

1. North American Electric Reliability Corporation (NERC)

The NERC mission is to ensure the reliability, resiliency, and security of the North American bulk power system (BPS). The BPS is made up of six regional entities¹² that provide the NERC with data, narratives, and assessments to independently evaluate long-term reliability, recognize trends, and identify emerging issues and potential risks for the upcoming 10-year period. The NERC develops a long-term reliability assessment (LTRA) annually based on known system changes as of July of the current year. The NERC is

subject to oversight by the Federal Energy Regulatory Commission (FERC).

Resource adequacy refers to the ability of an electricity system to meet the power demand of customers at all times, even during peak usage and potential outages. In the most recent LTRA released in December 2024 (2024 LTRA), the NERC identified increasing resource adequacy challenges for the upcoming 10 years as demand growth surges and power generators announce retirement plans.¹³ The NERC also identified a substantial number of the replacement generation resources as weather dependent and, thus, more variable and less reliable than the resources they would replace.

As part of its capacity and energy risk assessment, the 2024 LTRA identifies areas subject to potential future electricity supply shortfalls under normal and extreme weather conditions. The shortfall risks are categorized as “high risk,” “elevated-risk” and “normal-risk.” The 11 electric utilities covered by this interim final rule fall in areas categorized as either elevated-risk or normal-risk. As stated in the 2024 LTRA, elevated-risk areas meet resource adequacy criteria, but analysis indicates that extreme weather conditions are likely to cause a shortfall in area reserves. Eight of the 11 facilities fall within an elevated-risk area. Normal-risk areas are expected to have sufficient resources under a broad range of assessed conditions. The remaining three facilities fall within a normal-risk area.

The 2024 LTRA provides a risk summary for the areas categorized with an elevated risk.¹⁴ The risks for the MISO area (5 of the 11 facilities) were summarized as “Uncertainty around new resource additions and existing generator retirements results in resource adequacy risks. Above-normal generator outages during extreme weather can result in unserved energy or load loss.” Additionally, NERC determined that MISO’s “elevated risk” classification may shift to “high risk” in the 2028–2031 timeframe, depending on new resource additions/retirements.¹⁵ For the PJM area (2 of the 11 facilities), the risks were summarized as “Resource additions are not keeping up with generator retirements and demand growth. Winter seasons replace summer

¹⁰ Coletto Creek Power, “Annual Progress Report (§ 257.103(f)(2)(x)) for the Coletto Creek Power Plant Primary Ash Pond.” November 30, 2024.

¹¹ Intermountain Power Service Corporation, “October 2024 Annual Progress Report, Documenting the Continued Lack of Alternative Capacity and the Progress Towards the Closure of the Coal-Fired Boilers.” Oct. 4, 2024.

¹² The six regional entities overseen by NERC that monitor and enforce reliability standards for the BPS are: Midwest Reliability Organization (MRO), Northeast Power Coordinating Council (NPCC), ReliabilityFirst (RF), SERC Reliability Corporation (SERC), Texas Reliability Entity (Texas RE), and Western Electricity Coordinating Council (WECC).

¹³ NERC, “2024 Long-Term Reliability Assessment, December 2024, Updated July 15, 2025.”

¹⁴ NERC, 2024 LTRA, Table 1.

¹⁵ NERC, “Statement on NERC’s 2024 Long-Term Reliability Assessment,” June 17, 2025, <https://www.nerc.com/news/Pages/Statement-on-NEERC%E2%80%99s-2024-Long-Term-Reliability-Assessment.aspx>.

as the higher-risk periods due to generator performance and fuel supply issues.” Finally, for the SPP area (1 of the 11 facilities), the risks were summarized as “Potential energy shortfalls during peak summer and winter conditions arise from low wind conditions and natural gas fuel risk.”

2. U.S. Department of Energy (DOE)

In July 2025, the DOE published a report titled “Evaluating the Reliability and Security of the United States Electric Grid” to evaluate U.S. electric grid reliability and security (“2025 DOE Report”).¹⁶ The report highlights significant reliability risks facing the nation’s electrical grid due to current retirement schedules and insufficient incremental additions. The report concludes that, if current retirement schedules and incremental additions proceed as anticipated, most regions will face unacceptable reliability risks within five years and the Nation’s electric power grid will be unable to meet expected demand for artificial intelligence, data centers, manufacturing, and industrialization while maintaining affordable and reliable access to energy. The report identifies the retirement of power-generating assets, particularly coal and natural gas sources, as exacerbating resource adequacy issues, with 104 Gigawatts of firm capacity slated for retirement by 2030. This capacity is not being replaced equivalently, posing risks of outages during unfavorable weather conditions for wind and solar generation. Even in the absence of retirements, the DOE’s model predicts a significant increase in outage risks by 2030.

IV. Revised Deadline for Cessation of Operations and Unit Closure

A. Revision to Section 257.103(f)(2)(iv)(B)

This rule proposes to extend the regulatory deadline for owners and operators that intend to cease coal-fired generation to complete the closure of their unlined CCR surface impoundments larger than 40 acres. Specifically, this deadline would be extended by three years, from October 17, 2028, to October 17, 2031. See revised section 257.103(f)(2)(iv)(B). This rule change would provide regulatory flexibility to allow placement of CCR in the affected impoundments, and therefore coal-fired electricity

generation, to continue at these facilities for up to three additional years.

EPA is proposing this rule change in response to concerns that retirement of coal-fired power generating assets is exacerbating the resource adequacy problem. Given NERC’s assessment that resource adequacy risk may increase in the MISO area from “elevated” to “high” in the 2028–2031 period, the Agency is proposing a 3-year extension to the deadline to cease placing waste in the relevant impoundments. This extension would allow coal-fired generation to continue for up to three additional years, specifically between 2028 and 2031 at these power plants. Furthermore, an extension of less than three years (*e.g.*, one year) would not address resource adequacy concerns in the MISO area between 2028–2031. Currently EPA also lacks a basis to extend the deadline for more than three years. The Agency requests comment on the selected length of deadline extension and whether it should be shorter or longer than the proposed three years.

This rule’s proposed deadline extension is anticipated to impact eleven Part A Rule facilities with unlined CCR surface impoundments that are still operating pursuant to the alternative closure requirements under section 257.103(f)(2). Five of these facilities fall within the electric power market operated by MISO, two within PJM, and one facility each in ERCOT, Northwest, Southwest, and SPP. As noted in Section III.C., the majority (*i.e.*, eight) of these facilities are located in elevated-risk regions according to the 2024 LTRA.

This rule does not propose to revise the deadline for boiler cessation and unit closure applicable to CCR surface impoundments 40 acres or smaller. Section 257.103(f)(2)(iv)(A) required the owners and operators of these smaller impoundments both to cease operation of the coal-fired boiler and complete closure of the CCR surface impoundment no later than October 17, 2023. All of these CCR surface impoundments have ceased receiving CCR and non-CCR waste streams and those impoundments are no longer operating pursuant to the alternative closure provisions under section 257.103(f)(2). Therefore, a similar 3-year extension of the October 17, 2023, deadline would provide no relief.

Based on the information presented in Unit III of this preamble, EPA expects that most of the facilities with a pending Part A demonstration would choose to continue operating their coal-fired boiler(s) past their current anticipated closure date. The Agency realizes that

some facilities are unlikely to change their current closure timelines because they are on schedule to cease operating coal-fired boilers in the near future (*e.g.*, Naughton), are required to cease coal-fired generation by a specific date (*e.g.*, Big Cajun II), or have plans to transition to generating electricity from a different fuel source (*e.g.*, Intermountain, Coletto Creek). However, most facilities operating under a pending Part A demonstration have the capability of adjusting their unit closure timeframes, and EPA anticipates that these facilities would continue to operate during the proposed extended timeframe, thereby helping to mitigate potential resource adequacy concerns.

Additionally, EPA notes that a separate Agency action issued under the Clean Water Act proposes to extend the deadline for certain coal-fired electric generating units planning to close in the future (90 FR 47693, October 2, 2025).¹⁷ If finalized as proposed this extension would prevent premature closure due to other forcing mechanisms like CWA regulatory requirements taking effect. In other words, the 11 facilities impacted by today’s proposal should be able to avail themselves of the 3-year extension proposed here without that timeframe being cut short by other retirement deadlines. EPA is not aware of other such broadly-applicable retirement deadlines that could effectively cut short the extension being proposed today, but the Agency requests public comment on any such complicating factors. Thus, EPA expects that the proposed deadline extension would directly promote resource adequacy by allowing most of the 11 facilities affected by this proposal to continue to operate for up to three additional years.

In particular, EPA expects that extended coal-fired boiler operation would address resource adequacy in the electric power markets of MISO, SPP, and PJM. EPA estimates that continued operation of boilers currently slated to close would result in approximately 3,200 MW of capacity remaining online for up to three additional years in MISO. This additional capacity would address nearly 10% of the generation capacity retirements anticipated for MISO by 2030.¹⁸ In SPP, extended operation of

¹⁷ This rulemaking, proposed under the CWA, would (among other things) extend the date for existing steam electric power plants that would seek to achieve permanent cessation of coal combustion by December 31, 2034, to submit a notice of planned participation (NOPP), allowing utilities additional time to assess evolving power demand needed to inform operational planning and decision making.

¹⁸ According to the 2025 DOE Report, MISO is anticipated to experience retirement of 32,345 MW of generation capacity by 2030.

¹⁶ U.S. Department of Energy, “Evaluating the Reliability and Security of the United States Electric Grid,” July 2025. This report is available in the rulemaking docket for this action.

coal-fired facilities would maintain 1,056 MW of generating capacity for up to three additional years, addressing about 14% of the anticipated capacity retirements expected by 2030.¹⁹ Likewise, EPA estimates that continued operation of the affected units in PJM would preserve approximately 2,200 MW of capacity for up to three additional years, which would offset about 13% of the anticipated retirements in PJM by 2030.²⁰

EPA requests public comment on the potential benefits and benefits reductions of extending the alternative closure deadline as described in this action. In particular, the Agency is soliciting feedback on the potential for this action, if finalized, to address projected energy supply shortages discussed in Unit III.C of this preamble, especially for baseload and peak load reliability regionally. The Agency anticipates that the additional flexibility created by allowing operators subject to the provisions of section 257.103(f)(2)(iv)(B) will result in extended operation of the associated coal-fired boilers and delay the capacity reductions described in the DOE Report. However, EPA requests public comment on the likelihood of this outcome, and specifically requests further information regarding which operators are likely to avail themselves of the additional three years to complete closure of their unlined surface impoundment(s).

EPA also requests public input on the accuracy and recency of information presented in Unit III of this preamble regarding the facilities potentially impacted by this action. The facility-specific summaries reflect the information presented in the 2020 Demonstrations submitted by these facilities and information in their most recent annual progress reports, most of which were prepared in around November 2024, but EPA realizes that plans may have changed since these files were submitted and updated last.

B. Implementation Considerations of the Deadline Extension

The existing regulations require facilities operating pursuant to a Part A Rule extension request to prepare an annual progress report. Section 257.103(f)(2)(x). The purpose of the annual progress report is to document the continued lack of alternative disposal capacity and the progress towards the closure of the CCR surface

impoundment. As stated in the Part A Rule preamble, the annual progress report “must include any delays in the anticipated cease receipt of waste date and closure completion date that was submitted in the demonstration materials.” 85 FR 53550 (Aug. 28, 2020). Because the extended deadline will not automatically be applied to all current extension requests, owners and operators that will operate pursuant to the new extended deadline should document that fact in their next annual progress report. Owners and operators are not required to resubmit to EPA an updated demonstration documenting the new extended deadline.

Facilities operating CCR surface impoundments pursuant to Section 257.103(f)(2) are currently subject to comprehensive regulations requiring groundwater monitoring and, where necessary, remediation of contaminated groundwater. These regulations detail the types of groundwater monitoring systems required, sampling and analysis requirements, detection monitoring programs, assessment monitoring programs, assessment of corrective measures, selection of remedies, and implementation of groundwater corrective action programs. See Sections 257.90–257.98. Any facility that will operate pursuant to the new extended deadline in section 257.103(f)(2)(iv)(B) will continue to be subject to these requirements to detect releases of CCR constituents of concern and take action to remedy contamination when it exceeds established health thresholds.

Furthermore, the regulations also required facilities to submit a risk mitigation plan as part of their Part A demonstration. Section 257.103(f)(2)(v)(B). As stated in the Part A Rule, the risk mitigation plan describes the measures that will be taken to expedite any required corrective action to address any increased risk from continued operation of the CCR surface impoundment, which EPA will review as part of determining whether to grant the extension. If additional measures to mitigate the risk are necessary to ensure that the statutory standard is met, EPA will require those as a condition of granting the extension. 85 FR 53548.

V. The Projected Economic Impact of This Action

A. Introduction

EPA estimated the costs and benefits of this action in a Regulatory Impact Analysis (RIA), which is available in the docket for this action.

B. Affected Universe

The universe of facilities units and facilities affected by this proposed rule consists of CCR surface impoundments at coal fired electric utility plants that currently qualify for an extension under section 257.103(f)(2) based on their submission of a complete demonstration to EPA in compliance with the provisions of the 2020 CCR Part A Rule. EPA has identified 13 units at 11 facilities that may be affected by this proposed rule.

C. Baseline Costs

The baseline costs of this action consist of costs related to the closure of CCR surface impoundments in accordance with the requirements of the 2015 CCR final rule by October 17, 2028, the deadline for closure specified in the 2020 CCR Part A Rule.

D. Costs and Benefits of This Proposed Rule

This proposed rule is expected to result in cost savings from time value of money impacts (*i.e.*, the value of delaying expenses) from conducting closure activities later than those activities would have otherwise occurred. Affected units will now be able to complete closure by October 17, 2031, an extension of 3 years. The estimated annualized cost savings attributable to this proposed rule are approximately \$7–12 million per year when discounting at 3% and \$17–27 million per year when discounting at 7%.

EPA also considered, but did not quantify, the potential effects of this proposed rule on grid reliability and air emissions. This action would enhance grid reliability by allowing a subset of coal-fired boilers to continue to operate beyond their currently scheduled retirement date. For a discussion of the potentially affected facilities and electric power markets see section III.B of the preamble. EPA expects the impact of this proposed rule on air emissions to be marginal because the number of potentially affected facilities who would be eligible for the extension and able to burn coal for an additional three years represents a small subset of the overall fleet of coal-fired generating units in the United States. Additional details can be found in the RIA for this action.

VI. Statutory and Executive Order Reviews

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

¹⁹ According to the 2025 DOE Report, MISO is anticipated to experience retirement of 7,318 MW of generation capacity by 2030.

²⁰ According to the 2025 DOE Report, PJM is anticipated to experience retirement of 16,706 MW of generation capacity by 2030.

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

This action is a significant regulatory action as defined under section 3(f)(1) of Executive Order 12866. Accordingly, it was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to E.O. 12866 review have been documented in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, “Regulatory Impact Analysis: Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals from Electric Utilities; Extension of an Alternative Closure Requirement Deadline,” is available in the docket and is briefly summarized in Unit V of this preamble.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is expected to be an Executive Order 14192 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in EPA’s analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. An Information Collection Request covering the information collection activities contained in the existing Disposal of Coal Combustion Residuals From Electric Utilities ICR has been submitted for OMB’s approval under the temporary OMB control number 2050–0223.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule relieves regulatory burden on the small entities subject to the rule. The proposed rule does not change current regulatory burdens, but rather just extends the timeline necessary to meet them, which should reduce impacts on all affected facilities. The rule relieves burden by extending the deadline for owners and operators of coal boilers operating under a Part A demonstration to cease operation and

close their unlined CCR surface impoundment. This delay affords all entities, including small entities, more time to comply, and reduces compliance costs by pushing them into the future. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million (adjusted annually for inflation) or more (in 1995 dollars) 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.

F. 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.

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

This action does not have Tribal implications as specified in Executive Order 13175. The rule relieves burden by extending the deadline for owners and operators of coal boilers operating under a Part A demonstration to cease operation and close their unlined CCR surface impoundment. This rule does not impose any additional requirements. Thus, Executive Order 13175 does not apply to this action.

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

Executive Order 13045 directs federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The 2020 Part A final rule required all units applying for extensions to demonstrate full compliance with the applicable provisions of the 2015 final CCR rule at 40 CFR 257 subpart D, including all structural integrity, corrective action and other requirements needed to

safeguard human health and the environment. Because all units potentially affected by this proposed rule are subject to a Part A extension, it is unlikely that changes in closure schedule under this proposed rule will have any specific impacts to children’s health. However, EPA’s *Policy on Children’s Health* applies to this action. Information on how the Policy was applied is available under “Children’s Environmental Health” in the Supplementary Information section of this preamble.

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

This action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This proposed rule affords certain facilities additional flexibility in the timing of the closure of their coal-fired boilers and CCR disposal unit. Assuming that these facilities are economically optimizing their operations, this additional flexibility is not expected to result in any adverse impacts or outcomes with regard to fuel supply or production, or energy costs. The proposed rule, which reduces costs on a time value of money basis, will not result in any adverse electricity price or energy market impacts.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

List of Subjects in 40 CFR Part 257

Environmental protection, Beneficial use, Coal combustion products, Coal combustion residuals, Coal combustion waste, Disposal, Hazardous waste, Landfill, Surface impoundment.

Lee Zeldin,
Administrator.

For the reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

PART 257—CRITERIA FOR CLASSIFICATION OF SOLID WASTE DISPOSAL FACILITIES AND PRACTICES

■ 1. The authority citation for part 257 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a)(1), 6927, 6944, 6945(a) and (d); 33 U.S.C. 1345(d) and (e).

■ 2. Amend § 257.103 by revising paragraph (f)(2)(iv)(B) to read as follows:

§ 257.103 Alternative closure requirements.

* * * * *

(f) * * *

(2) * * *

(iv) * * *

(B) For a CCR surface impoundment that is larger than 40 acres, the coal-fired boiler(s) must cease operation, and the CCR surface impoundment must complete closure no later than October 17, 2031.

* * * * *

[FR Doc. 2025–21597 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION**National Highway Traffic Safety Administration****49 CFR Parts 563 and 585**

[Docket No. NHTSA–2025–0050]

RIN 2127–AM78

Event Data Recorders

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); response to petitions for reconsideration.

SUMMARY: NHTSA published a final rule on December 18, 2024, in response to a mandate of the Fixing America's Surface Transportation Act (FAST Act) to establish the appropriate recording period in NHTSA's Event Data Recorder (EDR) regulation (49 CFR part 563). The final rule amended the pre-crash data capture requirements of EDRs by increasing the recording duration and sample rate from 5 seconds at 2 Hz to 20 seconds at 10 Hz. The agency received three petitions for reconsideration from the Alliance of Automotive Innovation, the EDR Committee of SAE International, and FCA US LLC (a subsidiary of Stellantis N.V.) in response to the final rule. NHTSA is proposing to delay the compliance date from September 1, 2027, to September 1, 2028, and implement a phase-in period for EDRs to meet the new requirements.

DATES: Comments must be received by December 29, 2025. In compliance with the Paperwork Reduction Act, NHTSA is also seeking comment on a reinstatement with modification to a previously approved information collection. For additional information, see the Paperwork Reduction Act section under the Rulemaking Analyses and Notices section below. All

comments relating to the information collection requirements should be submitted to NHTSA and to the Office of Management and Budget (OMB) at the address listed in the **ADDRESSES** section on or before December 29, 2025.

Proposed Compliance Dates: NHTSA proposes delaying the compliance date and adopting a 4-year phase-in period to comply with the requirements in 49 CFR part 563 as amended by the final rule published on December 18, 2024, final rule, “Event Data Recorders.” The proposal would require that 25 percent of a manufacturer's applicable vehicles produced from September 1, 2028, to August 31, 2029, comply with Part 563, followed by 50 percent from September 1, 2029, to August 31, 2030, 75 percent from September 1, 2030, to August 31, 2031, and 100 percent on and after September 1, 2031. NHTSA also proposes that vehicles manufactured in two or more stages or that are altered are not required to comply with the rule until on or after September 1, 2031. Small-volume and limited-line manufacturers would be required to comply beginning on September 1, 2032. The proposal would permit voluntary early compliance.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- **Mail:** Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- **Hand Delivery or Courier:** West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call 202–366–9332 before coming.

- **Fax:** 202–493–2251.

Regardless of how you submit your comments, please mention the docket number of this document.

Comments on the proposed information collection requirements should be submitted to: Office of Management and Budget at www.reginfo.gov/public/do/PRAMain. To find this particular information collection, select “Currently under Review—Open for Public Comment” or use the search function. It is requested that comments sent to the OMB also be sent to the NHTSA rulemaking docket

identified in the heading of this document.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov, or the street address listed above. Follow the online instructions for accessing the dockets.

Confidential Business Information: If you claim that any of the information in your comment (including any additional documents or attachments) constitutes confidential business information within the meaning of 5 U.S.C. 552(b)(4) or is protected from disclosure pursuant to 18 U.S.C. 1905, please see the detailed instructions given under the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy Act: Please see the Privacy Act heading under the Regulatory Analyses section of this document.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may contact Joshua McNeil, Office of Crashworthiness Standards (joshua.mcneil@dot.gov). For legal issues, you may contact Eli Wachtel, Office of the Chief Counsel (eli.wachtel@dot.gov). You can reach these officials by phone at 202–366–1810. Address: National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Executive Summary
- II. Background
 - A. Event Data Recorders and Part 563
 - B. Rulemaking Actions
- III. Summary of Petitions for Reconsideration
- IV. Discussion and Analysis
 - A. Lead Time and Phase-In Schedule
 - B. Cost Estimates
 - C. Basis for December 2024 Final Rule and Benefits
 - D. Industry Standards
 - E. CDR Development
- V. Rulemaking Analyses and Notices

I. Executive Summary

In this notice of proposed rulemaking (NPRM), NHTSA responds to petitions for reconsideration of a final rule published December 18, 2024, that amended the data capture requirements

of event data recorders (EDRs) to specify a 20-second recording duration and a 10 Hz sample rate.¹ The primary purpose of an EDR is to record technical information for a brief period before, during, and after a collision, aiding in post-crash analysis and reconstruction. The data recorded by the EDR provides a snapshot of the vehicle dynamics that can aid crash investigators in assessing the performance of specific safety equipment, including air bag deployment strategies, air bag operation, and event severity. This information can also help NHTSA and others identify potential opportunities for safety improvements in current and future vehicles and implement more effective safety regulations. Manufacturers are not required to install EDRs in their vehicles. However, EDRs that are voluntarily installed must meet the requirements NHTSA has established in 49 CFR part 563 (Part 563).

NHTSA received three petitions for reconsideration of the December 2024 final rule from the Alliance of Automotive Innovation (Auto Innovators),² the EDR Committee of SAE International (SAE),³ and FCA U.S. LLC (FCA), a subsidiary of Stellantis N.V.⁴ NHTSA is granting the petitions for reconsideration in part and proposing to adopt the compliance timeline requested by both SAE and Auto Innovators in their respective petitions. This modified timeline would provide manufacturers with an extended lead time and a phase-in to allow them to integrate the necessary EDR and Airbag Control Module (ACM)⁵ architecture changes within their current model development cycles without disrupting existing product plans. The agency's proposal balances the need for enhanced crash data, as mandated by the FAST Act, with practical industry constraints to ensure these safety advancements can be implemented effectively across the entire vehicle fleet. However, NHTSA is not proposing to adjust the recording duration and sample rate requirements for EDRs as finalized in the December 2024 final rule. These technical specifications represent enhancements to vehicle crash data collection capabilities that will support more comprehensive crash

investigations. NHTSA is deferring a final decision on reconsideration until after review of comments received in response to this NPRM.

NHTSA is proposing to extend the lead time for initial compliance with the requirements of the December 18, 2024, rule by one year from September 1, 2027, to September 1, 2028. In addition, NHTSA proposes adding a phase-in period that would require 25 percent of a manufacturer's fleet equipped with EDRs to be compliant with the requirements of the final rule beginning in the first year of compliance, and an additional 25 percent each year after that, until the fleet is fully compliant in the fourth year. This matches the lead time and phase-in period suggested in the petitions received from Auto Innovators and SAE. We seek comment on all aspects of this proposal.

II. Background

A. Event Data Recorders and Part 563

NHTSA established Part 563 on August 28, 2006, setting forth requirements for the accuracy, collection, storage, survivability, and retrievability of data in vehicles equipped with EDRs. NHTSA does not mandate EDRs on vehicles, but, if vehicles are equipped with EDRs, the EDRs must meet specific data capture requirements as outlined in Tables I–III of Part 563. Table I lists 15 data elements all EDRs subject to Part 563 are required to record, along with the recording interval (duration) and data sample rate. Table II lists optional data elements that EDRs are not required to capture, but if recorded, are subject to the recording interval (duration) and sample rate for each listed data element in Table II.⁶ All data elements in Tables I and II must be reported according to the range, accuracy, and resolution in Table III of Part 563. Since Part 563 became fully effective on September 1, 2012, the adoption of EDRs has been nearly universal. NHTSA's internal analysis estimates 99.5 percent of model year 2021 passenger cars and other vehicles with a gross vehicle weight rating (GVWR) of 3,855 kilograms (kg) (8,500 pounds) or less are equipped with EDRs that comply with Part 563.

EDRs are often integrated into a vehicle's ACM, the electronic system used to determine the deployment timing for air bags. EDRs record data related to restraints and deployment internal to the ACM, often at or just after a triggering event, referred to as crash

data. EDRs also record data from other existing vehicle sensors such as wheel speed or accelerator pedal position that is transferred from the vehicle's other onboard computers (electronic control units or ECUs) to the ACM via controller area network (CAN) or similar communication. The EDR temporarily stores this pre-crash data in a buffer. When a triggering event occurs, pre-crash and crash data are stored in non-volatile memory, so it survives even if the vehicle battery is damaged or disconnected in the crash. This data can include vehicle speed, throttle position, brake application, steering angle, seatbelt use, and air bag deployment timing. If a vehicle is equipped with an EDR, it must contain at a minimum the data outlined in Table I of Part 563, but manufacturers can add additional data elements at their discretion. The required pre-crash data elements in Table I include: (1) speed, vehicle indicated; (2) engine throttle, percent full (or accelerator pedal, percent full); and (3) service brake, on/off. The storage size of this data is considered small, often just kilobytes, because the EDR only stores a short interval of data around the time of a triggering event.

B. Rulemaking Actions

On June 22, 2022, pursuant to section 24303 of the Fixing America's Surface Transportation Act (FAST Act), Public Law 114–94 (December 4, 2015), NHTSA issued an NPRM to amend Part 563.⁷ The NPRM relied on the findings of an EDR Duration Study⁸ required by the FAST Act and information gathered from NHTSA's defects investigation experience which indicated that EDR data can be used to assess whether a vehicle operated properly at the time of an event, or to help detect undesirable operations. The June 2022 NPRM proposed extending the recording interval and data sample rate of pre-crash data elements under Part 563 from 5 seconds at 2 Hz to 20 seconds at 10 Hz (*i.e.*, an increase from 2 samples per second to 10 samples per second).

NHTSA explained in the June 2022 NPRM that extending the recording duration from 5 to 20 seconds would help capture critical data on the initiation of pre-crash actions and maneuvers for most crashes. The June 2022 NPRM acknowledged the proposed changes could result in additional costs, as more memory would be required to store the increased amount of pre-crash data. However, the agency explained the

¹ 89 FR 102810 (December 18, 2024).

² NHTSA–2024–0084–0005.

³ NHTSA–2024–0084–0004.

⁴ NHTSA–2024–0084–0003.

⁵ Manufacturers have different names for this module including the Airbag Control Unit (ACU), Sensing Diagnostic Module (SDM), Restraints Control Module (RCM), Powertrain Control Module (PCM), Supplemental Restraint System (SRS), and the like. In this document, ACU and ACM may be used interchangeably as both terms were presented in the petitions for reconsideration.

⁶ Two data elements in Table II are listed as “if equipped,” meaning if a vehicle has the specified equipment, the specified information must be recorded.

⁷ 87 FR 37289 (June 22, 2022).

⁸ Event Data Recorder Duration Study [Appendix to a Report to Congress. Report No. DOT HS 813 082B], 2022, <https://doi.org/10.21949/1530244>.

additional memory could be incorporated into the existing or planned memory design in vehicles, based on the relatively small amount of memory necessary to record the pre-crash data for 20 seconds at 10 Hz.⁹ NHTSA proposed an effective date of the first September 1 one year after the publication of the final rule, noting that a one-year lead time was appropriate because increasing the required pre-crash data would not require any additional hardware or a substantial redesign of either the EDR or the vehicle and would likely require only minimal software changes.

After reviewing comments submitted in response to the June 2022 NPRM, NHTSA published a final rule on December 18, 2024, that increased the pre-crash recording duration and sample rate requirements of the seven pre-crash data elements in Part 563 from 5 seconds to 20 seconds, as proposed.¹⁰ Per the statutory mandate of the FAST Act, the December 2024 final rule aimed to establish the appropriate period for EDRs to capture and record vehicle-related data to provide sufficient information to investigate the cause of motor vehicle crashes.

NHTSA explained in the December 2024 final rule that the increased recording duration will provide more details on actions taken prior to crashes. Specifically, vehicle actions such as running a stop sign or red light could be captured in full and included in crash reconstruction when supplemented with roadway and traffic control information. The increased recording duration could also help capture any corrective maneuvers taken by a vehicle prior to an initial road departure or braking and acceleration actions taken in the approach stage before traversing large intersections. NHTSA explained that the increased sample rate will help clarify the interpretation of pre-crash data, including braking and steering actions taken by the vehicle, especially in situations where an action occurs just prior to impact (between 0.5 seconds prior to impact and the time of impact). The agency also noted that this could both help reduce potential uncertainty related to the relative timing of recorded data elements and assist with the identification of potential pedal

misapplication. The compliance date set by NHTSA for the December 2024 final rule was September 1, 2027, for vehicles equipped with an EDR. Small-volume or limited-line manufacturers were given until September 1, 2029, to comply, and altered or multi-stage manufacturers were given until September 1, 2030, to comply.

III. Summary of Petitions for Reconsideration

NHTSA regulations allow any interested person to petition the Administrator for reconsideration of a rule. Under NHTSA's regulations, petitions for reconsideration must provide an explanation why compliance with the rule is not practicable, is unreasonable, or is not in the public interest. In addition, petitions must be received within 45 days of the publication of the final rule. The Administrator may consolidate petitions relating to the same rule. The Administrator may issue a final decision on reconsideration without further proceedings or may provide opportunity for comment.¹¹

The agency received three petitions for reconsideration in response to the December 2024 final rule from Auto Innovators, SAE, and FCA.¹² In its petition, Auto Innovators stated that the changes to the pre-crash recording period and sample rate lack sufficient evidence of safety benefits and impose significant implementation burdens. The petition from Auto Innovators raised three main concerns. First, the petition stated that NHTSA's reliance on the EDR Duration Study in the December 2024 final rule without fully addressing comments to the June 2022 NPRM was inadequate.¹³ Second, the petition claimed that the two-year lead time in the final rule (compliance date of September 1, 2027) underestimated the complexity of changing the hardware and software for EDRs. The petition disputed NHTSA's claim that many EDRs can meet the new requirements with minor changes, citing needs for increased memory, energy, and redesigned components, which could strain supply chains and vehicle production cycles. Third, Auto Innovators stated that NHTSA's analysis in the December 2024 final rule

oversimplified the costs of compliance by focusing on component-level upgrades (e.g., capacitors, memory) and did not adequately consider broader redesign, validation, and recertification expenses for existing and late-stage development vehicles. The petition stated that capacitor size estimates differed by a factor of approximately 1,000 and that any changes to the number of capacitors could impact the vehicle architecture or onboard computers. Regarding crash data retrieval (CDR) tools, Part 563 mandates that manufacturers ensure commercially available tools for EDR data access and retrieval within 90 days of a vehicle's first sale if the vehicle is equipped with an EDR. 49 CFR 563.12. Auto Innovators highlighted the unaddressed cost, complexity, and lead time for updating CDR tools for all manufacturers within the 90-day window, especially without a phase-in period.

Auto Innovators sought a revised rule that balances safety goals with practical implementation to maintain the current level of EDR implementation. The petitioner suggested a three-year lead time with a four-year phase-in (25/50/75/100 percent). NHTSA understands this suggestion to mean the first September 1 that is three years from the publication of the December 2024 final rule. Auto Innovators requested that NHTSA reassess the feasibility and benefits of the December 2024 final rule and conduct a more thorough cost-benefit analysis with industry input. It also urged alignment with international standards.¹⁴

SAE stated that the December 2024 final rule is impractical, unreasonable, and not in the public interest. SAE noted that it advocates for the use of EDRs as tools for crash reconstruction, not driver behavior monitoring devices, and stated that the prior requirements (5 seconds at 2 Hz) are sufficient. SAE stated that 20 seconds of pre-crash data captures speculative actions unrelated to crash causation, posing risks of privacy violations and misleading reconstructions without crash-site evidence. SAE disputed NHTSA's reliance on the EDR Duration Study, asserting that no evidence supports the benefit of longer data capture durations. Regarding CDR tools, while most manufacturers use Bosch CDR products,¹⁵ SAE stated that due to the

⁹ NHTSA estimated that an increase in pre-crash recording duration from 5 seconds to 20 seconds with an increase in recording frequency from 2 Hz to 10 Hz would require 1.33 Kb of additional memory for one event.

¹⁰ Three data elements are included in Table I of part 563 as mandatory elements to be recorded if an EDR is equipped. Four data elements are included in Table II of part 563 as having to meet certain requirements if they are recorded by the EDR.

¹¹ 49 CFR 553.35, 553.37.

¹² NHTSA–2024–0084–0005 (Auto Innovators), NHTSA–2024–0084–0004 (SAE), and NHTSA–2024–0084–0003 (FCA).

¹³ Auto Innovators and SAE in response to the June 2022 NPRM critiqued aspects of the EDR Duration Study, including the model year of the vehicles, the small set of data elements, and the basis for concluding that 20 seconds of pre-crash data enhances crash analysis beyond the previous requirement of 5 seconds.

¹⁴ UN ECE No. 160 maintains the 5 seconds/2 Hz minimum requirements for pre-crash recorded data elements.

¹⁵ In comments on the June 2022 NPRM, Bosch suggested exempting older, soon-to-be discontinued models from the amendments, arguing that capturing new vehicle technologies is more

complicated connection and interface requirements for each manufacturer, Bosch would have to develop new software and possibly all new interfaces and software to read EDR data. SAE asserted this development process will be further complicated by longer imaging times for each device due to the increased amount of EDR data.¹⁶

SAE also stated that a two-year timeline is inadequate and would require manufacturers to implement extensive hardware and software updates and perform rigorous testing and validation, and could prompt manufacturers to disable EDRs, thus undermining safety goals. SAE recommended retaining the previous recording requirements or adopting a phase-in and hosting a workshop to assess manufacturer needs if the new recording requirements are maintained. SAE also questioned NHTSA's cost justification process under the Office of Management and Budget (OMB) guidelines, requesting related documentation and cited the cost estimates provided by Auto Innovators in response to the June 2022 NPRM.¹⁷ SAE recommended that NHTSA reconsider the final rule, citing minimal societal benefit, privacy risks, and industry burdens. SAE also requested a three-year lead time with a four-year phase-in (25/50/75/100 percent).

FCA's petition stated that it supports the goal of extending the EDR capture and recording period but that the two-year lead time is impractical to implement. FCA explained that the design changes necessary to update their EDRs do not align with existing product plans, necessitating costly, expedited investments. FCA asserted that a more gradual timeline would reduce costs significantly, potentially to zero, by aligning with standard industry product lifecycles. FCA suggested a 4-year phase-in as follows: September 1, 2027: 25 percent compliance; September 1, 2028: 50 percent compliance; September 1, 2029: 75 percent compliance; September 1, 2030: 100

beneficial than extending recording duration. While supporting a sample rate increase to 10 Hz for better capture events such as braking, steering, and lane change maneuvers, Bosch noted that even this change alone would require software and hardware modifications.

¹⁶ SAE notes there are currently 22 manufacturers and 55 brands supported worldwide by the tool, and these changes would require a substantial workload. SAE mentions that other EDR data collection tool suppliers (e.g., GIT) would be negatively impacted.

¹⁷ Auto Innovators estimated the cost burden for the initial year would be \$231.36 million. That estimate is \$8.4 million per manufacturer (for 17 manufacturers) for development and testing plus the incremental EDR module cost (\$5.40) times the number of vehicles fitted in that year.

percent compliance. FCA stated that this timeline would allow current vehicle models to be phased out under existing rules while new models adopt the updated standards, enabling cost-effective validation through crash tests. FCA stated that removing EDR functionality due to timeline pressures would not align with its safety and transparency goals as it remains committed to maintaining EDR technology. FCA emphasized that EDRs aid post-crash analysis rather than directly saving lives.

IV. Discussion and Analysis

NHTSA is proposing to grant the petitions in part by extending the lead time and implementing a phase-in schedule to align the changes made to EDRs more closely with the production life cycles of vehicles. The added lead time and phase-in period aims to ease the financial burden associated with the testing and development stages necessary to validate the EDR functions as intended and not compromise performance of the air bag deployment systems. The three petitions expressed concerns with the following general areas of the final rule: lead time, costs and benefits, estimate of hardware and software changes, basis for recording duration, industry standards, and CDR development. The sections below examine each topic in turn, discussing the petitions and explaining the agency's response.

A. Lead Time and Phase-In Schedule

Lead Time

Auto Innovators, SAE, and FCA stated that the final rule's compliance date (September 1, 2027) is impractical, forcing a redesign of current EDRs and electrical systems across all vehicle models. They recommended a phase-in schedule: Auto Innovators and SAE suggested an additional year of lead time (a total of three years of lead time) followed by a four-year phase-in (25/50/75/100 percent), while FCA suggested a four-year phase-in (25/50/75/100 percent) starting from the rule's compliance date (a total of two years of lead time).¹⁸

NHTSA has tentatively determined that the implementation timeline for the December 2024 final rule may create unnecessary redesign and validation costs, especially with regards to late-stage design and in-market vehicles, and

¹⁸ The final rule required all vehicles equipped with an EDR to meet the new requirements beginning two years following the first September 1 after publication. Because the final rule was published in December 2024 the compliance date was set as September 1, 2027.

may risk some such vehicles no longer being equipped with EDRs. Therefore, the agency is proposing to amend Part 563 by extending the lead time by one year and adding the phase-in period suggested by Auto Innovators and SAE in their petitions for reconsideration. This option is being proposed in part because, based on the cost estimates below, the extra year of lead time compared to the schedule suggested by FCA would reduce costs further. This option is also being proposed to lower the risk that NHTSA and a wide range of stakeholders could lose access to valuable EDR data. Since Part 563 is an "if equipped" standard, manufacturers retain discretion over whether to install EDRs in vehicles, provided any EDRs that are installed on light vehicles required to have frontal air bags comply with the regulation's requirements. If some manufacturers determine that costs or technical issues involved in bringing certain models into compliance with the requirements in the December 2024 final rule outweigh the benefits of including EDRs, they may discontinue EDR installation.

NHTSA's December 2024 final rule set an effective date of September 1, 2027. The approximately two years and eight months provided more implementation flexibility than the June 2022 NPRM's proposed one-year lead time. This decision was partially based on manufacturer feedback suggesting some EDRs already had the memory, energy, and processing power for capturing 20 seconds of pre-crash data at 10 Hz. NHTSA did acknowledge that even EDRs with the capability to record 20 seconds of pre-crash data would require testing and validation to ensure compliance and to prevent interference with air bag timing. However, NHTSA admitted that it lacked the data to estimate how many EDRs in the current vehicle fleet possess the necessary hardware for the new requirements, given adequate time for software changes and system validation.

The agency acknowledges that manufacturers may have insufficient time to adopt in full the new requirements which could force limiting some of their EDR functionality. As highlighted in the petitions, the development cycle and installation of EDRs can span three to four years, and manufacturers may have already finalized EDRs for model years 2026 through 2030, making immediate changes costly.

Therefore, to lower the risk that NHTSA and a wide range of stakeholders could lose access to valuable EDR data due to burdensome cost and redesign constraints imposed

by the December 2024 final rule's original timeline, NHTSA proposes to extend the lead time and add a phase-in schedule for vehicles equipped with EDRs to meet the pre-crash recording requirements. The agency did not intend for manufacturers to remove EDR functionality and did not suggest manufacturers remove EDRs to meet the requirements in the December 2024 final rule. NHTSA anticipates that a phase-in schedule would allow manufacturers to implement the necessary EDR and ACM architecture changes in existing model development cycles. This approach also ensures the agency's continued collection of valuable data from vehicles with EDRs that do not yet meet the new requirements.

The phase-in schedule, excluding small volume and multi-stage manufacturers, would be as follows for vehicles equipped with EDRs:

- 25 percent of the vehicles manufactured on or after September 1, 2028, and before September 1, 2029.
- 50 percent of the vehicles manufactured on or after September 1, 2029, and before September 1, 2030.
- 75 percent of the vehicles manufactured on or after September 1, 2030, and before September 1, 2031.
- 100 percent of the vehicles manufactured on or after September 1, 2031.

Small-volume manufacturers and multi-stage manufacturers would not be subject to the phase-in. Small-volume manufacturers would have an additional year to comply, and multi-stage manufacturers and alterers would have two additional years. As proposed, the requirements would apply beginning September 1, 2032, to small-volume manufacturers or limited-line manufacturers and September 1, 2033, for vehicles manufactured by manufacturers producing altered

vehicles or vehicles in two or more stages.

Cost Savings Associated With This Proposed Rule

In developing this response to the petitions, NHTSA analyzed potential cost savings from different lead time extensions and phase-in schedules. Table 1 summarizes societal cost saving based on a three-year phase-in with a one-year lead time extension. The proposed lead time and phase-in (one-year extension followed by 25/50/75/100 percent phase-in) means the first model year (MY) impacted by the final rule would apply to consumers purchasing new MY2029 vehicles. The phase-in would begin on September 1, 2028, with 25 percent compliance of vehicles between September 1, 2028, and August 31, 2029, increasing to 50 percent and 75 percent in the following years, and 100 percent after August 31, 2031. This phase-in is projected to save \$9.95 to \$25.14 million in 2028, \$6.63 to \$16.76 million in 2029, and \$3.32 to \$8.38 million in 2030. The lead time extension itself is projected to save an additional \$13.26 to \$33.52 million in 2027, resulting in total quantified savings of \$33.15 to \$83.80 million from 2027 to 2030. When discounting at three percent, the cost savings is approximately \$29.77 million to \$75.23 million. When discounting at seven percent, the cost savings is approximately \$25.95 million to \$65.57 million.

In comments to the June 2022 NPRM and the petitions addressed in this document, manufacturers documented significant implementation costs associated with the mandatory updates to EDRs across their vehicle fleets. The estimates from Auto Innovators indicated that mid-cycle engineering modifications would require an estimated \$231.36 million in redesign expenditures in the first year followed

by \$88.56 in subsequent years. The additional lead time and phase-in schedule would enable manufacturers to integrate compliant EDRs into their standard development timelines, eliminating the need for costly expedited engineering solutions. NHTSA's conservative estimate of \$33.15 million to \$83.80 million in quantified savings represents only the direct costs avoided through this approach to extend the lead time and offer a phase-in. The agency does not have the information to estimate the additional cost savings from manufacturers not having to make substantial design changes to vehicle models in the middle of their production cycle. Manufacturers may find further unquantifiable savings through flexibility and technological advancements, allowing them to phase out older EDRs lacking the necessary capabilities to record for 20 seconds at 10 Hz without requiring extensive modifications. For example, NHTSA anticipates that emerging storage technologies could replace Electrically Erasable Programmable Read-Only Memory (EEPROM), currently a common method for recording EDR data. These newer technologies would allow data to be written to non-volatile memory more quickly than EEPROM, potentially reducing the reserve power needed if the vehicle battery fails during the data recording process. If manufacturers determine that alternatives like flash memory or ferroelectric random-access memory (FRAM) are suitable for EDRs and cost-effective solutions, the implementation costs may decrease. In addition, as technology advances, manufacturers can expect either reduced prices for existing memory components or increased storage capacity at comparable price points, without significantly increasing the physical size of EDR modules.

TABLE 1—SUMMARY OF COST SAVINGS BY MODEL YEAR 3-YEAR PHASE-IN AND 1-YEAR EXTENSION
[Millions]

Model year	Phase in schedule (%)	Incremental cost		Estimated cost savings to society	
		FRE	Supplemental analysis	Quantified	Unquantified
2028	0	\$13.26–\$33.52	\$0	\$13.26–\$33.52	Potential reduction in cost due to increased flexibility, developments in technology, and learning.
2029	25	13.26–33.52	3.32–8.38	9.95–25.14	
2030	50	13.26–33.52	6.63–16.76	6.63–16.76	
2031	75	13.26–33.52	9.95–25.14	3.32–8.38	
2032+	100	13.26–33.52	13.26–33.52	0	
Total Cost Savings				33.15–83.80	

Note: Values may not sum due to rounding.

B. Cost Estimates

The petitioners raised several issues with the cost analysis in the December 2024 final rule. Broadly, petitioners raised issues with the component hardware and software cost estimates NHTSA used, such as an inadequate estimate of the changes to the amount of memory and reserve power that would be needed, the costs associated with additional validation and testing needed to meet the new requirements, and the component estimates in the final regulatory evaluation (FRE)¹⁹ supplementing the December 2024 final rule.

NHTSA is not adjusting its cost estimates with regard to hardware and software changes in response to the petitions. It is not clear from the Auto Innovators' petition what aspect of the December 2024 final rule petitioners are requesting be amended if such a change in cost estimates is made. Nonetheless, the agency previously underestimated the amount of time some manufacturers would need to design, test, and validate EDRs after implementing hardware and software changes. The proposed additional lead time and phase-in period should alleviate the financial burden associated with manufacturers having to upgrade EDRs across their models. It may also allow manufacturers to increase the amount of non-volatile memory and RAM, if needed, and validate the correct transfer rates and frequencies of the required data (Table I elements). It would also allow manufacturers to assess whether more reserve energy is necessary to write the increased amount of data within the EDR or additional reserve energy sources for maintaining power for other vehicle systems after a triggering event. Furthermore, this proposed extended period may facilitate the testing and development of newer, faster data processing and writing technologies, potentially reducing the reserve energy needed for reliable data capture.

Regarding the component hardware itself, NHTSA estimated in the June 2022 NPRM and December 2024 final rule that the amount of memory required to meet the new requirements would increase from 0.90 kB to 2.26 kB per event, not accounting for necessary memory buffers. While the June 2022 NPRM initially anticipated near-zero costs based solely on memory upgrades, the December 2024 final rule's analysis was updated to account for EDRs lacking sufficient hardware to accommodate the increased data. This revised cost analysis included

incremental expenses for upgrading all hardware components necessary for buffering and writing the data to non-volatile memory. Feedback indicated many manufacturers use flash memory (standalone or in microcontrollers) with capacities up to 96 kB to capture EDR data. A few manufacturers are recording pre-crash data at 10 Hz (but not for 20 seconds) while many already capture pre-crash data elements not listed as required data elements to capture in Table I of Part 563. Based on the estimated data increase of 1.33 kB per event, NHTSA continues to believe manufacturers either have sufficient memory in a subset of their EDRs or can develop EDRs with more memory, if needed, to capture 20 seconds of data given enough time to test and develop EDRs.

Based on the amount of data to be recorded with the extended duration and the current amount of memory available in EDRs (32 Kb to 96 Kb), NHTSA did not anticipate a need for more reserve power in the December 2024 final rule and has not received information to change this assumption in the NPRM. Another study on EDRs published by NHTSA (referred to as the EDR Technologies Study in the NPRM and 2024 Final Rule)²⁰ showed a decade-long trend of manufacturers moving from EEPROM to flash memory, which should reduce the amount of time necessary to write the data and consequently the reserve energy needed to complete the writing process. Manufacturers had indicated to NHTSA that some EDR modules already possess the hardware capabilities (in terms of memory, power, and controller specifications) to meet the new requirements. Therefore, NHTSA is not adjusting its cost estimates for hardware and software changes.

NHTSA is not altering the component-level costs presented in the FRE supplementing the December 2024 final rule. The agency provided a cost range (\$13.26 million to \$33.52 million annually) based on the hardware specification of two EDR platforms to meet the new Part 563 requirements, which were components selected to meet the AEC-Q200 standard. NHTSA is addressing an error in the analysis, however, that the FRE should have used "mF" (millifarad) instead of "µF" (microfarad) as the standard unit of capacitors. The agency's cost estimates have therefore been revised to include upgrading from a 3.3-mF capacitor to a 6.8-mF capacitor. The average unit prices, after a 70 percent discount, were \$0.24 for 3.3-mF capacitors (based on 24

quotes) and \$0.26 for 6.8-mF capacitors (based on 13 quotes), resulting in a \$0.02 difference, consistent with the component-level upgrade cost presented in the FRE.

C. Basis for December 2024 Final Rule and Benefits

The petitions from Auto Innovators and SAE critiqued the EDR Duration Study that NHTSA used to justify extending the recording duration and criticized NHTSA discussion in the June 2022 NPRM and December 2024 final rule of the benefits of the increased amount of EDR pre-crash data.²¹ Auto Innovators requested that NHTSA reconsider the EDR duration and frequency specifications and examine the possibility that similar safety benefits can be attained through less burdensome requirements. SAE requested that NHTSA retain the prior 5-second duration and 2-Hz recording frequency for pre-crash data elements or adopt a phase-in schedule for manufacturers to meet the new EDR requirements.

NHTSA is not proposing to amend these aspects of Part 563. Auto Innovators claims NHTSA has not demonstrated the potential safety benefits of the extended recording duration. However, Congress mandated NHTSA conduct a study to determine an appropriate recording duration for providing sufficient information to investigate the cause of motor vehicle crashes. Following the submission of this study's findings, the FAST Act required NHTSA to issue a final rule. The June 2022 NPRM and December 2024 Final Rule extensively detail the benefits of increasing the recording duration.

The fundamental purpose of Part 563 is to ensure EDRs record data "valuable for effective crash investigations and for analysis of safety equipment performance." The EDR Duration Study's findings clearly indicate that the current 5-second pre-crash recording duration under Part 563 fails to capture the initiation of pre-crash braking and steering maneuvers in a significant number of cases. The study showed that extending the pre-crash recording duration would capture a greater amount of information regarding a vehicle's actions leading up to a triggering event, thereby increasing the value of EDR data for crash investigations. Based on these findings, a 20-second recording duration is necessary to ensure that the initiation of

¹⁹ NHTSA-2024-0084-0002.

²⁰ DOT HS 812 929.

²¹ Auto Innovators and SAE offered similar comments in response to the June 2022 NPRM (87 FR 37289).

pre-crash actions and crash avoidance maneuvers are captured for the majority of crashes. This recording duration will increase the utility of the recorded information, potentially leading to further advancements in the safety of both current and future vehicles. Furthermore, the study concluded that a more comprehensive understanding of pre-crash actions will aid in the evaluation of crash avoidance systems (such as lane departure warning, lane keeping assist, forward collision avoidance, automatic emergency braking, and intersection safety assistance systems), even if specific data from these systems is not directly reported by the EDR.

The EDR Duration Study aimed to identify the necessary recording duration for investigating crash causation. The study was not directed to prove that increasing the recording duration of EDR data would increase safety or to estimate the cost of design changes associated with extending the recording duration. NHTSA believes the study provides a robust basis for increasing the recording duration to 20 seconds based on the study's finding that a 5-second window often misses significant pre-crash actions, particularly for road departure and intersection crashes. The study showed that 5 seconds is insufficient to capture crucial information, such as the initiation of crash avoidance maneuvers like braking and steering, in a considerable percentage of crashes where EDRs are triggered. For example, the study demonstrated that approximately 35 percent of drivers that applied brakes did so outside of the 5-second window prior to impact. The actions of the vehicles captured beyond 5 seconds would assist investigators with crash reconstruction. Moreover, the study indicated that 20 seconds would encompass the 90th percentile of recording duration needed for lane departure, intersection, and rear-end crashes.

NHTSA acknowledges the vehicles used in the study lacked modern safety features that could have intervened within five seconds of the crash event. However, current regulations do not mandate that EDRs capture the status of active safety systems. While manufacturers may voluntarily record data on modern safety features in their EDRs, it could not be consistently included in the study. Consequently, the current five-second recording duration of most EDRs inherently restricts the ability to analyze crash causation beyond that timeframe. The study used the 100-Car Naturalistic Driving Study (NDS) and Strategic

Highway Research Program (SHRP 2) NDS because they contained data extending beyond five seconds, enabling researchers to analyze vehicle actions in rear-end crashes, lane departures, and the approach and traversal stages when passing through an intersection.

The EDR Duration Study was conducted in two phases. Phase one used existing crash data from NHTSA's database to analyze how often the five-second EDR recording duration failed to capture the start of driver actions before crashes. This phase established that the five-second requirement was inadequate and proved the need for longer recording durations. Phase two used naturalistic driving study data to examine the complete timeline of driver pre-crash actions (beyond five seconds pre-crash). Researchers used this real-world driving behavior data to determine what EDR recording duration would be needed to capture when drivers first began taking pre-crash actions. Phase two of the EDR Duration Study examined newer vehicles than the vehicles examined in Phase one. Though active safety features are not required to be recorded in EDRs, Phase two found that increased recording time could allow for more voluntary recording of active safety systems. The activation times for ABS in that data ranged from two to nine seconds before a crash, further demonstrating the inadequacy of a five-second recording duration to capture all relevant pre-crash vehicle dynamics. Moreover, understanding vehicle dynamics and driver behavior that occur before ABS activation is crucial for comprehensive crash causation analysis. These earlier timeframes can contain the initial decision points and driving patterns that precipitate the conditions leading to ABS engagement. Without this extended timeline data, investigators could miss critical information about steering and braking inputs, early avoidance maneuvers, and progressive system interventions that form the complete causal chain of events.

The EDR Duration Study referred to driver "behavior" and "actions" interchangeably. Literature has shown that crash causation is often related to driver error, so understanding a driver's actions pre-crash is crucial. Therefore, the study focused on the duration needed to capture a driver's actions pre-crash in full, which is within the scope of EDR data collection for effective crash investigation purposes. Consequently, the Phase two objective was precisely to determine a recording duration that enhances the certainty of capturing the complete timeline of pre-crash actions.

NHTSA underscores that achieving the most accurate reconstruction of events triggering EDR recording necessitates the continued integration of all pertinent information alongside EDR data. When analyzing data more likely to represent normal driving behavior and less directly related to crash causation, the EDR Duration Study specifically examined actions preceding the event, such as changes in steady-state vehicle velocity and the earliest instances of braking. A finding from Phase two of the study was that a 20-second pre-crash data window would encompass the 90th percentile of the required recording duration for the analyzed crash modes (lane departure, intersection, and rear-end) and associated crash avoidance maneuvers.

NHTSA emphasizes that the 20-second extended recording duration will be particularly beneficial in analyzing intersection crashes. These crashes typically involve an approach stage as the vehicle nears the intersection and a traversal stage in which the vehicle is exposed in the intersection. Based on the EDR Duration Study, extending the pre-crash recording duration to 20 seconds would capture approximately 90 percent of all intersection events and nearly all braking scenarios, compared to less than one percent with the five-second recording duration. The extended duration, combined with the increased sample rate, would document the complete sequence of driver actions from initial accelerator release (occurring up to 12 seconds pre-crash) through brake application (up to 10 seconds pre-crash) to any evasive maneuvers. With typical intersection events lasting 10–19 seconds depending on the configuration, the longer duration would capture the entire approach and traversal phases. This EDR data would reveal the critical decision points across various intersection sizes and approach types (*e.g.*, complete stops, low-speed rolling stops, high-speed rolling stops). Similarly, in road departure crashes, longer durations could capture more complete information on gradual lane departures and corrective steering or braking maneuvers initiated by the driver before the initial departure from the roadway. This extended duration could also prove valuable in analyzing events occurring on larger highways, potentially capturing the actions of a vehicle as it approaches a stop sign or a signaled intersection, even across multiple lanes.

Regarding privacy concerns, NHTSA reaffirms that EDRs do not record personally identifiable information. The

data captured is routinely overwritten, preserving data only when specific crash events meet the defined trigger threshold in Part 563. Extending the pre-crash recording duration to 20 seconds is not anticipated to heighten privacy concerns, as it involves no new or significantly altered technology for collecting, storing, or disseminating personally identifiable information. Moreover, the Driver Privacy Act of 2015, enacted under the FAST Act after Part 563's establishment, legally designates the vehicle owner or lessee as the owner of EDR data. Retrieval of this recorded data is strictly limited to purposes of enhancing motor vehicle safety and safety research (provided the data remain non-personally identifiable), or with the explicit consent of the vehicle owner or through a lawful court or administrative order. These privacy protections should effectively address expressed concerns while enabling the agency to fulfill the FAST Act's mandate of establishing an appropriate recording period within NHTSA's EDR regulation.

Auto Innovators and SAE stated that there will remain an ongoing need to collect supplementary data like police reports and ADAS event data for a more complete understanding of crash causation. NHTSA agrees that supplemental information (e.g., police reports) remains crucial for researchers, law enforcement, and reconstructionists to analyze vehicle and crash dynamics. However, NHTSA clarifies that the FAST Act's mandate specifically addressed pre-crash recording duration, not the addition of ADAS event data to be captured by EDRs. In response to SAE's caution against solely relying on EDR data, NHTSA emphasizes that the December 2024 final rule did not suggest abandoning the consideration of other critical factors in crash investigations. Instead, the increased data, coupled with a higher sample rate, aims to offer a more complete understanding of the pre-crash actions of the vehicle and their interplay. NHTSA is not mandating the inclusion of additional data elements beyond those listed in Part 563 at this time. However, the extended lead time and phase-in period proposed in this notice could present an opportunity for manufacturers to modernize the EDRs being equipped in their vehicles if they so choose. This timeframe may allow manufacturers the flexibility to develop and rigorously test EDR systems capable of capturing crucial information related to crash avoidance technologies and

other ADAS like SAE Level 2 systems.²² This includes data that is already available within other existing ECUs onboard the vehicle, but that may not currently be recorded by the EDR. Notably, some manufacturers already equip vehicles with EDRs that capture status for systems like adaptive cruise control, automatic emergency braking, forward collision warning, and lane departure warning, which are all data elements beyond the current Part 563 requirements. Manufacturers may voluntarily add data elements to be recorded by their EDRs, provided these additions do not compromise the EDR's ability to meet the minimum data capture requirements outlined in Part 563. This modernization could significantly enhance the richness and utility of EDR data for future safety research and analysis.

Therefore, NHTSA is not proposing to amend the 20-second recording duration and 10 Hz sample rate requirements for EDRs as finalized in the December 2024 final rule.

D. Industry Standards

In its petition, SAE asked for more information on the process associated with the Office of Management and Budget (OMB) Circular No. A-119 (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities). SAE asked whether NHTSA sent any documentation to OMB in justification of the costs and the rationale per OMB's conformity assessment activities (per OMB A-119).²³ SAE requested the agency to identify and share such documentation. Auto Innovators stated that NHTSA should have exercised discretion when implementing the FAST Act requirement and instead

²² SAE Level 2 refers to features that provide steering and brake/acceleration support to the driver. An example would be lane centering and adaptive cruise control features functioning at the same time while the driver constantly supervises the support features to maintain safety.

²³ In relevant part, OMB A-119 states, "In those circumstances where an agency elects to use or develop a government unique standard in lieu of using a voluntary consensus standard, Section 12(d) of the NTTAA requires the agency to submit a report describing the reason(s) to OMB. Under the Circular, this report is submitted to OMB through the National Institute of Standards and Technology (NIST). For more information on reporting, see Sections 9-11 of this Circular." Section 9 of OMB A-119 states, "At minimum, your agency must have the ability to provide to OMB, through NIST, (1) a report on the agency's use of government-unique standards in lieu of voluntary consensus standards, along with an explanation of the reasons for such 33 usages, as required by Section 12(d) of the NTTAA and as described in Section 5c of this Circular; and (2) a summary of your agency's activities undertaken to carry out the provisions of this Circular."

should have sought to align with established industry standards and international regulatory requirements more closely.

NHTSA carefully considered the consensus standards applicable to EDR data elements in establishing Part 563 and in amending Part 563 in the December 2024 final rule.²⁴ NHTSA declined to adopt the voluntary consensus standards for the pre-crash recording because such a decision would be inconsistent with the best available information to the agency and conflict with the outcome of a study required by the FAST Act. The factors the agency considered when implementing a conformity assessment program are discussed in the preamble to the December 2024 final rule with regards to the requirements of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104-113). These factors have not changed, and NHTSA declines to propose amending Part 563 pursuant to align with industry consensus standards.

With regards to material submitted pursuant to Circular A-119, the Circular A-119 annual report does not typically include rulemaking and decision information, such as costs. It identifies where NHTSA regulations incorporate a government-unique standard in lieu of an industry-developed voluntary consensus standard and explains the reasons for such usage.

E. CDR Development

Part 563 mandates that manufacturers ensure commercially available tools for EDR data access and retrieval within 90 days of a vehicle's first sale if the vehicle is equipped with an EDR. 49 CFR 563.12. NHTSA acknowledges the concerns raised by Auto Innovators, SAE, and Bosch regarding EDR data accessibility. The additional lead time and phase-in proposed here should enable producers of EDR data retrieval tools to update, test, and validate their new products, including direct-to-module cables, ensuring their capability to retrieve the EDR data effectively.

V. Rulemaking Analyses and Notices

Executive Orders 12866 and 14192

This proposed rule does not meet the criteria of a "significant regulatory action" under Executive Order (E.O.) 12866. Therefore, the Office of

²⁴ There are consensus standards related to EDRs, most notably standards published by SAE (J1698—Event Data Recorder), Institute of Electrical and Electronics Engineers (IEEE) (Standard 1616, IEEE Standard for Motor Vehicle Event Data Recorder) and UN Regulation No. 160 (which was followed by UN Regulation No. 160 Revision 1).

Management and Budget (OMB) has not reviewed this proposed rule under that Executive Order.

Under E.O. 14192, a deregulatory action is an action that has been finalized and has total costs less than zero. The rulemaking, if finalized as proposed, would be an E.O. 14192 deregulatory action.

The requirements specified in the final rule provide benefits through the use of EDR data in crash defects investigations. However, the FRE was not able to quantify those benefits. The FRE accounted for the incremental costs associated with the final rule. Incremental costs reflect the increase in total lifetime cost for end users as a result of meeting the requirements specified in the final rule relative to costs incurred under the baseline. Therefore, the incremental costs reflected in the analysis are associated with upgrading currently compliant EDRs to meet the requirements specified in the final rule. Those incremental costs reflect hardware and software costs, as well as costs for redesign, validation, and labor. The FRE estimated that the incremental cost associated with the final rule ranged from approximately \$13.26 million to \$33.52 million in 2022 dollars.

This rulemaking is a deregulatory action under E.O. 14192 because it would reduce the implementation burden associated with the December 2024 final rule, which increased the pre-crash data recording duration and sample rate required under 49 CFR part 563. While the substantive requirements adopted in the December 2024 final rule remain unchanged, the agency is proposing to modify the compliance schedule in response to petitions for reconsideration that identified implementation challenges and risk of unintended consequences.

Petitioners explained that the original compliance date imposed a rigid and accelerated timeline that did not align with typical vehicle development cycles. These conditions would have imposed high compliance costs, disrupted product planning, and could have resulted in the removal or disabling of EDR functionality in some vehicle models—undermining the very safety objectives the rule was designed to advance. Quantified cost savings are discussed in more detail above, in Section IV.A. Also, as noted, the safety benefits of the December 2024 final rule were unquantified. This was similar when NHTSA established Part 563. This was due to the difficulties in estimating both the exact portion of benefits creditable to an increased amount of EDR data after a standard is

implemented or a safety countermeasure is developed and of quantifying how the benefits to safety research and emergency response translate to improved vehicle safety. Nonetheless, the agency acknowledges that it is likely the implementation timeline created a regulatory failure by imposing a disproportionate burden relative to those benefits, particularly for vehicle platforms in late-stage design or production. The agency seeks comment with information which may aid this determination. This proposed rule would correct that failure.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), agencies must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). No regulatory flexibility analysis is required, however, if the head of an agency or an appropriate designee certifies that the rule does not have a significant economic impact on a substantial number of small entities. I certify that this rulemaking action would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is provided below.

The proposed delay in the compliance date and creation of a phase-in period would reduce the burden on small entities by providing more time to comply with the new requirements. In addition, limited line²⁵ and small-volume manufacturers²⁶ would only need to produce vehicles with EDRs that meet the requirements, if the vehicle is equipped with an EDR, on or after September 1, 2032. Manufacturers producing altered vehicles or vehicles in two or more stages would have one additional year, until September 1, 2033, for compliance.

NHTSA has concluded that this proposed rule would not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included.

²⁵ Limited line manufacturer means a manufacturer that sells three or fewer carlines, as that term is defined in 49 CFR 583.4, in the United States during a production year.

²⁶ Small-volume manufacturer as defined in § 571.127, “Automatic emergency braking systems for light vehicles,” is an original vehicle manufacturer that produces or assembles fewer than 5,000 vehicles annually for sale in the United States.

Executive Order 13132 (Federalism)

NHTSA has examined this rule pursuant to E.O. 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with States, local governments, or their representatives is mandated beyond the rulemaking process. The agency has concluded that this rule does not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The rule does 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.”

This proposed rule would amend an existing regulation. When 49 CFR part 563 was promulgated in 2006, NHTSA explained its view that any State laws or regulations that prohibit the types of EDRs addressed by Part 563 would create a conflict and therefore be preempted.²⁷ As a result, regarding this proposed rule, NHTSA does not believe there are current State laws or regulations for EDRs that conflict with Part 563.

Executive Order 12988 (Civil Justice Reform)

With respect to the review of the promulgation of a new regulation, section 3(b) of E.O. 12988, “Civil Justice Reform” (61 FR 4729, February 7, 1996), requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. This document is consistent with that requirement.

Pursuant to this E.O., NHTSA notes as follows. The issue of preemption is discussed above, in the section discussing E.O. 13132 (Federalism). NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceedings before they may file suit in court.

²⁷ The 2006 final rule promulgating 49 CFR part 563 discussed preemption at length. See 71 FR 50907, 51029 (August 28, 2006).

Executive Order 13609 (Promoting International Regulatory Cooperation)

E.O. 13609, “Promoting International Regulatory Cooperation” (77 FR 26413, May 1, 2012), promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

The agency is currently participating in the negotiation and development of technical standards for Event Data Recorders in the United Nations Economic Commission for Europe (UNECE) World Forum for Harmonization of Vehicle Regulations (WP.29). As a signatory member, NHTSA is obligated to initiate rulemaking to incorporate safety requirements and options specified in Global Technical Regulations (GTRs) if the U.S. votes in the affirmative to establish the GTR. No GTR for EDRs has been developed at this time. NHTSA has analyzed this proposed rule under the policies and agency responsibilities of E.O. 13609 and has determined this rulemaking would have no effect on international regulatory cooperation.

National Environmental Policy Act

The Department has analyzed the environmental impacts of this notice of proposed rulemaking pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*). Pursuant to 49 CFR 1.81, the Secretary has delegated the “functions” under NEPA to the Administrators “as they relate to the matters within the primary responsibility of each Operating Administration.” NHTSA has determined that this proposed rule is categorically excluded pursuant to 23 CFR 771.118(c)(4). Categorical exclusions are actions identified in an agency’s NEPA procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). This rulemaking, which proposes to amend the regulations regarding Event Data Recorders to extend the lead time and establish a four-year phase-in, is categorically excluded pursuant to 23 CFR 771.118(c)(4) (Planning and administrative activities not involving or leading directly to construction, such as: Training, technical assistance and research; promulgation of rules, regulations, directives, or program guidance; approval of project concepts; engineering; and operating assistance to transit authorities to continue existing

service or increase service to meet routine demand). NHTSA does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), a Federal agency must request and receive approval from OMB before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. On May 28, 2025, and November 18, 2025, NHTSA published notices and requests for comment on a reinstatement with modification of a previously approved information collection to collect information regarding a reporting and recordkeeping requirement to facilitate enforcement of updates to FMVSS No. 208, “Occupant crash protection.” Those documents also requested to rename the Information Collection Request (ICR) associated with OMB Control No. 2127–0535 as “49 CFR part 585; Phase-In Reporting Requirements” and to consolidate all phase-in reporting requirements including in 49 CFR part 585 in that ICR. This proposed rule would establish new information collection requirements for phase-in reporting and record retention requirements related to EDRs. The ICR for a reinstatement with modification of a previously approved information collection described below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and the expected burden.

Agency: National Highway Traffic Safety Administration (NHTSA).

Title: Phase-In Reporting Requirements.

OMB Control Number: 2127–0535.

Form Number: N/A.

Type of Request: Reinstatement with modification of a previously approved information collection.

Type of Review Requested: Regular.

Requested Expiration Date of

Approval: 3 years from date of approval.

Summary of the Collection of

Information: This collection would require manufacturers of passenger cars, multipurpose passenger vehicles, trucks, and buses with a gross vehicle weight rating of 3,855 kg (8,500 pounds) or less that are equipped with EDRs to provide motor vehicle production data for the following four years: September 1, 2028, to August 31, 2029; September

1, 2029, to August 31, 2030; September 1, 2030, to August 31, 2031; and September 1, 2031, to August 31, 2032. Manufacturers would annually submit a report, and maintain records related to the report, concerning the number of such vehicles that meet the EDR requirements of Part 563 during the phase-in of those requirements.

Description of the Need for the Information and Proposed Use of the Information: The purpose of the reporting requirements would be to aid the agency in determining whether a manufacturer of passenger cars, multipurpose passenger vehicles, trucks, and buses with a GVWR of 3,855 kg (8,500 pounds) or less and an unloaded vehicle weight of 2,495 kg (5,500 pounds) or less, has complied with the event data recorder requirements during the phase-in of those requirements.

Affected Public: The respondents are manufacturers of passenger cars, multipurpose passenger vehicles, trucks, and buses having a gross vehicle weight rating of 3,855 kg (8,500 pounds) or less that are equipped with EDRs.

Estimated Number of Respondents: Approximately 22 vehicle manufacturers.

Estimated Total Annual Burden Hours: NHTSA estimates that the total annual hour burden is 22 hours.

The annual burden involves the tasks of collection of the information required by the annual report as well as placing the information in a form suitable for record keeping and data retrieval. Because almost all the information required is already recorded by the manufacturers as part of their production control and tracking systems, a nominal assessment of half a burden hour per respondent is estimated for data retrieval and report preparation and half a burden hour per respondent for the record keeping of the data. Therefore, NHTSA estimates that the average total burden for submitting data will be 11 hours per year (22 manufacturers × .5 hours = 11 hours) and estimates that the average total burden for record retention will be 11 hours per year (22 manufacturers × .5 hours = 11 hours). NHTSA estimates the labor costs associated with these labor hours using hourly labor rates published by the Bureau of Labor Statistics (BLS). BLS estimates that hourly wages represent approximately 70.2 percent of total compensation for private industry workers.²⁸ For the labor costs associated

²⁸ See Table 1. Employer Costs for Employee Compensation by ownership (June 2025), available at <https://www.bls.gov/news.release/pdf/ecec.pdf> (accessed September 12, 2025).

with this ICR, NHTSA uses the mean hourly wage of \$40.64 per hour for “Technical Writers” (occupational code 27–3042) for the Motor Vehicle Manufacturing Industry (Sectors 31, 32,

and 33)²⁹ and applies the 70.2 percent factor to find the total compensation rate of \$57.89 per hour (\$40.64 per hour divided by 0.705). The total annual labor cost associated with the burden

hours is estimated to be \$1,273.58 (time burden of 22 hours × \$57.89 cost per hour).

TABLE 1—ESTIMATED ANNUAL BURDEN HOURS AND LABOR COST

Information collection	Number of respondents	Total annual burden hours per respondent	Hourly labor cost	Total annual labor cost per respondent	Total annual burden hours	Total annual labor cost
Phase-In Reporting	22	.5	\$57.89	\$28.95	11	\$636.79
Phase-In Recordkeeping	22	.5	57.89	28.95	11	636.79
Total	22	1	57.89	57.89	22	1,273.58

Estimated Total Annual Burden Cost: \$0

NHTSA estimates that there are no costs associated with the proposed information collection other than labor costs associated with the burden hours.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department’s estimate of the burden of the proposed information collection; (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 the use of automated collection techniques or other forms of information technology.

National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), “all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.” Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies, such as SAE. The NTTAA directs agencies to provide Congress, through OMB, explanations when the agency decides not to use available and applicable voluntary consensus standards. The

NTTAA requires agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. In the December 2024 final rule, NHTSA provided a discussion of why that final rule declined to use voluntary consensus standards. This discussion remains applicable to this proposed rule which would not change aspects of Part 563 for which there are voluntary consensus standards. Please refer to Section IV.D for discussion of voluntary consensus standards in regard to OMB Circular A–119.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditures by States, local or Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation with base year of 1995) in any one year. This proposed rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMR) for State, local and Tribal governments, or the private sector of \$100 million or more in any one year (as adjusted for inflation). Thus, the rulemaking is not subject to the requirements of sections 202 and 205 of the UMR.

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

E.O. 13175, “Consultation and Coordination With Indian Tribal Governments” (65 FR 67249, November 6, 2000) requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on

policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. NHTSA has assessed the impact of this proposed rule on Indian tribes and determined that this proposed rule would not have tribal implications that require consultation under E.O. 13175.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL–14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, or labor union.). You may review DOT’s complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, (Volume 65, Number 70; Pages 19477–78).

Plain Language Requirement

E.O. 12866 and E.O. 13563 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

²⁹ See May 2023 National Industry-Specific Occupational Employment and Wage Estimates,

NAICS 336100—Motor Vehicle Manufacturing, available at <https://www.bls.gov/oes/2023/may/>

[naics4_336100.htm#27-0000](https://www.bls.gov/naics4_336100.htm#27-0000) (accessed September 12, 2025).

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
 - Does the rule contain technical language or jargon that is not clear?
 - Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
 - Would more (but shorter) sections be better?
 - Could we improve clarity by adding tables, lists, or diagrams?
 - What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this proposal.

Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda twice a year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number indicated in this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21) NHTSA established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

If you are submitting comments electronically as a PDF (Adobe) file, NHTSA asks that the documents be submitted using the Optical Character Recognition (OCR) process, thus allowing NHTSA to search and copy certain portions of your submissions.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at <https://www.transportation.gov/regulations/>

dot-information-dissemination-quality-guidelines.

How can I be sure that my comments were received?

If you wish the Docket to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, the Docket will return the postcard by mail.

How do I submit confidential business information?

You should submit a redacted "public version" of your comment (including redacted versions of any additional documents or attachments) to the docket using any of the methods identified under **ADDRESSES**. This "public version" of your comment should contain only the portions for which no claim of confidential treatment is made and from which those portions for which confidential treatment is claimed has been redacted. See below for further instructions on how to do this.

You also need to submit a request for confidential treatment directly to the Office of Chief Counsel. Requests for confidential treatment are governed by 49 CFR part 512. Your request must set forth the information specified in Part 512. This includes the materials for which confidentiality is being requested (as explained in more detail below); supporting information, pursuant to § 512.8; and a certificate, pursuant to § 512.4(b) and part 512, Appendix A.

You are required to submit to the Office of Chief Counsel one unredacted "confidential version" of the information for which you are seeking confidential treatment. Pursuant to § 512.6, the words "ENTIRE PAGE CONFIDENTIAL BUSINESS INFORMATION" or "CONFIDENTIAL BUSINESS INFORMATION CONTAINED WITHIN BRACKETS" (as applicable) must appear at the top of each page containing information claimed to be confidential. In the latter situation, where not all information on the page is claimed to be confidential, identify each item of information for which confidentiality is requested within brackets: "[]."

You are also required to submit to the Office of Chief Counsel one redacted "public version" of the information for which you are seeking confidential treatment. Pursuant to § 512.5(a)(2), the redacted "public version" should include redactions of any information for which you are seeking confidential treatment (*i.e.*, the only information that should be unredacted is information for which you are not seeking confidential

treatment). NHTSA is currently treating electronic submission as an acceptable method for submitting confidential business information to the agency under Part 512. Please do not send a hardcopy of a request for confidential treatment to NHTSA's headquarters. The request should be sent to Dan Rabinovitz in the Office of the Chief Counsel at Daniel.Rabinovitz@dot.gov. You may either submit your request via email or request a secure file transfer link. If you are submitting the request via email, please also email a courtesy copy of the request to Eli Wachtel at eli.wachtel@dot.gov.

Will the Agency consider late comments?

We will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that the docket receives after that date. If the docket receives a comment too late for us to consider in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

How can I read the comments submitted by other people?

You may read the comments received by the docket at the address given above under **ADDRESSES**. The hours of the docket are indicated above in the same location. You may also see the comments on the internet. To read the comments on the internet, go to <https://www.regulations.gov>. Follow the online instructions for accessing the dockets.

Please note that even after the comment closing date, we will continue to file relevant information in the docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material. You can arrange with the docket to be notified when others file comments in the docket. See www.regulations.gov for more information.

Rulemaking Summary, 5 U.S.C. 553(b)(4)

For NHTSA's December 2024 EDR final rule, this NPRM proposes to delay the compliance date from September 1, 2027, to September 1, 2028. This NPRM also proposes to implement a phase-in period for EDRs to meet the new requirements. As required by 5 U.S.C. 553(b)(4), a summary of this rule can be found at www.regulations.gov, Docket No. NHTSA-2025-0050, in the **SUMMARY** section of this proposed rule.

List of Subjects**49 CFR Part 563**

Motor vehicle safety, Motor vehicles, Reporting and recordkeeping requirements.

49 CFR Part 585

Reporting and recordkeeping requirements.

In consideration of the foregoing, NHTSA proposes to amend 49 CFR chapter V as follows:

PART 563—EVENT DATA RECORDERS

■ 1. The authority citation for Part 563 continues to read as follows:

Authority: 49 U.S.C. 322, 30101, 30111, 30115, 30117, 30166, 30168; delegation of authority at 49 CFR 1.95.

■ 2. Add § 563.4 to read as follows:

§ 563.4 Certification for Phase-in.

(a) *Vehicle certification information.* At any time during the production years

ending August 31, 2029, August 31, 2030, August 31, 2031, and August 31, 2032, each manufacturer shall, upon request from the Office of Vehicle Safety Compliance, provide information identifying the vehicles (by make, model and vehicle identification number) that have been equipped with EDRs meeting the requirements of § 563.7(a) and (b). The manufacturer's designation of a vehicle as equipped with an EDR meeting these requirements is irrevocable.

(b) *Vehicles produced by more than one manufacturer.* For the purpose of calculating average annual production of vehicles for each manufacturer and the number of vehicles manufactured by each manufacturer under § 563.4(a), a vehicle produced by more than one manufacturer shall be attributed to a single manufacturer as follows:

(1) A vehicle which is imported shall be attributed to the importer.

(2) A vehicle manufactured in the United States by more than one

manufacturer, one of which also markets the vehicle, shall be attributed to the manufacturer which markets the vehicle.

(c) A vehicle produced by more than one manufacturer shall be attributed to any one of the vehicle's manufacturers specified by an express written contract, reported to the National Highway Traffic Safety Administration under 49 CFR part 585, between the manufacturer so specified and the manufacturer to which the vehicle would otherwise be attributed under § 563.4(b).

(d) For the purposes of calculating average annual production of vehicles for each manufacturer and the number of vehicles manufactured by each manufacturer under § 563.4(a), only count vehicles to which this regulation is applicable as specified § 563.3 and are equipped with an EDR.

■ 2. Revise § 563.7 to read as follows:

§ 563.7 Data elements.

(a) * * *

TABLE I TO § 563.7(a)—DATA ELEMENTS REQUIRED FOR ALL VEHICLES EQUIPPED WITH AN EDR

Data element	Recording interval/time ¹ (relative to time zero)	Data sample rate (samples per second)
Delta-V, longitudinal	0 to 250 ms or 0 to End of Event Time plus 30 ms, whichever is shorter.	100
Maximum delta-V, longitudinal	0–300 ms or 0 to End of Event Time plus 30 ms, whichever is shorter.	N/A
Time, maximum delta-V	0–300 ms or 0 to End of Event Time plus 30 ms, whichever is shorter.	N/A
Speed, vehicle indicated	–20 to 0 sec ⁴	4 10
Engine throttle, % full (or accelerator pedal, % full)	–20 to 0 sec ⁴	4 10
Service brake, on/off	–20 to 0 sec ⁴	4 10
Ignition cycle, crash	–1.0 sec	N/A
Ignition cycle, download	At time of download ³	N/A
Safety belt status, driver	–1.0 sec	N/A
Frontal air bag warning lamp, on/off ²	–1.0 sec	N/A
Frontal air bag deployment, time to deploy, in the case of a single stage air bag, or time to first stage deployment, in the case of a multi-stage air bag, driver.	Event	N/A
Frontal air bag deployment, time to deploy, in the case of a single stage air bag, or time to first stage deployment, in the case of a multi-stage air bag, right front passenger.	Event	N/A
Multi-event, number of event	Event	N/A
Time from event 1 to 2	As needed	N/A
Complete file recorded (yes, no)	Following other data	N/A

¹ Pre-crash data and crash data are asynchronous. The sample time accuracy requirement for pre-crash time is –0.1 to 1.0 sec (e.g., T = –1 would need to occur between –1.1 and 0 seconds.)

² The frontal air bag warning lamp is the readiness indicator specified in S4.5.2 of FMVSS No. 208, and may also illuminate to indicate a malfunction in another part of the deployable restraint system.

³ The ignition cycle at the time of download is not required to be recorded at the time of the crash, but shall be reported during the download process.

⁴ Except as provided in the following phase-in, for vehicles manufactured before September 1, 2031, the required recording interval is –5.0 to 0 sec relative to time zero and the required data sample rate is two samples per second. For vehicles manufactured on or after September 1, 2028 but before August 31, 2029, 25 percent of each manufacturer's vehicle production must have the recording interval and data sample rate displayed in this table. For vehicles manufactured on or after September 1, 2029 but before August 31, 2030, 50 percent of each manufacturer's vehicle production must have the recording interval and data sample rate displayed in this table. For vehicles manufactured on or after September 1, 2030 but before August 31, 2031, 75 percent of each manufacturer's vehicle production must have the recording interval and data sample rate displayed in this table. For vehicles manufactured before September 1, 2032 by a small-volume manufacturer or limited-line manufacturer, the required recording interval is –5.0 to 0 sec relative to time zero and the required data sample rate is two samples per second. For vehicles manufactured before September 1, 2033 by manufacturers producing altered vehicles or vehicles in two or more stages, the required recording interval is –5.0 to 0 sec relative to time zero and the required data sample rate is two samples per second.

(b) * * *

TABLE II TO § 563.7(b)—DATA ELEMENTS REQUIRED FOR VEHICLES UNDER SPECIFIED MINIMUM CONDITIONS

Data element name	Condition for requirement	Recording interval/time ¹ (relative to time zero)	Data sample rate (per second)
Lateral acceleration	If recorded ²	N/A	N/A
Longitudinal acceleration	If recorded	N/A	N/A
Normal acceleration	If recorded	N/A	N/A
Delta-V, lateral	If recorded	0–250 ms or 0 to End of Event Time plus 30 ms, whichever is shorter.	100
Maximum delta-V, lateral	If recorded	0–300 ms or 0 to End of Event Time plus 30 ms, whichever is shorter.	N/A
Time maximum delta-V, lateral	If recorded	0–300 ms or 0 to End of Event Time plus 30 ms, whichever is shorter.	N/A
Time for maximum delta-V, resultant	If recorded	0–300 ms or 0 to End of Event Time plus 30 ms, whichever is shorter.	N/A
Engine rpm	If recorded	–20 to 0 sec ⁵	⁵ 10
Vehicle roll angle	If recorded	–1.0 up to 5.0 sec ³	10
ABS activity (engaged, non-engaged)	If recorded	–20 to 0 sec ⁵	⁵ 10
Stability control (on, off, or engaged)	If recorded	–20 to 0 sec ⁵	⁵ 10
Steering input	If recorded	–20 to 0 sec ⁵	⁵ 10
Safety belt status, right front passenger (buckled, not buckled).	If recorded	–1.0 sec	N/A
Frontal air bag suppression switch status, right front passenger (on, off, or auto).	If recorded	–1.0 sec	N/A
Frontal air bag deployment, time to nth stage, driver ⁴	If equipped with a driver's frontal air bag with a multi- stage inflator.	Event	N/A
Frontal air bag deployment, time to nth stage, right front passenger ⁴ .	If equipped with a right front passenger's frontal air bag with a multi-stage inflator.	Event	N/A
Frontal air bag deployment, nth stage disposal, driver, Y/N (whether the nth stage deployment was for occupant restraint or propellant disposal purposes).	If recorded	Event	N/A
Frontal air bag deployment, nth stage disposal, right front passenger, Y/N (whether the nth stage deployment was for occupant restraint or propellant disposal purposes).	If recorded	Event	N/A
Side air bag deployment, time to deploy, driver	If recorded	Event	N/A
Side air bag deployment, time to deploy, right front passenger.	If recorded	Event	N/A
Side curtain/tube air bag deployment, time to deploy, driver side.	If recorded	Event	N/A
Side curtain/tube air bag deployment, time to deploy, right side.	If recorded	Event	N/A
Pretensioner deployment, time to fire, driver	If recorded	Event	N/A
Pretensioner deployment, time to fire, right front passenger ...	If recorded	Event	N/A
Seat track position switch, foremost, status, driver	If recorded	–1.0 sec	N/A
Seat track position switch, foremost, status, right front passenger.	If recorded	–1.0 sec	N/A
Occupant size classification, driver	If recorded	–1.0 sec	N/A
Occupant size classification, right front passenger	If recorded	–1.0 sec	N/A
Occupant position classification, driver	If recorded	–1.0 sec	N/A
Occupant position classification, right front passenger	If recorded	–1.0 sec	N/A

¹ Pre-crash data and crash data are asynchronous. The sample time accuracy requirement for pre-crash time is –0.1 to 1.0 sec (e.g., T = –1 would need to occur between –1.1 and 0 seconds.).

² “If recorded” means if the data is recorded in non-volatile memory for the purpose of subsequent downloading.

³ “vehicle roll angle” may be recorded in any time duration; –1.0 sec to 5.0 sec is suggested.

⁴ List this element n – 1 times, once for each stage of a multi-stage air bag system.

⁵ Except as provided in the following phase-in, for vehicles manufactured before September 1, 2031, the required recording interval is –5.0 to 0 sec relative to time zero and the required data sample rate is two samples per second. For vehicles manufactured on or after September 1, 2028 but before August 31, 2029, 25 percent of each manufacturer's vehicle production must have the recording interval and data sample rate displayed in this table. For vehicles manufactured on or after September 1, 2029 but before August 31, 2030, 50 percent of each manufacturer's vehicle production must have the recording interval and data sample rate displayed in this table. For vehicles manufactured on or after September 1, 2030 but before August 31, 2031, 75 percent of each manufacturer's vehicle production must have the recording interval and data sample rate displayed in this table. For vehicles manufactured before September 1, 2032 by a small-volume manufacturer or limited-line manufacturer, the required recording interval is –5.0 to 0 sec relative to time zero and the required data sample rate is two samples per second. For vehicles manufactured before September 1, 2033 by manufacturers producing altered vehicles or vehicles in two or more stages, the required recording interval is –5.0 to 0 sec relative to time zero and the required data sample rate is two samples per second.

PART 585—PHASE-IN REPORTING REQUIREMENTS

■ 3. The authority citation for part 585 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.95.

■ 4. Add Subpart P, consisting of § 585.142 through 585.148, to read as follows:

Subpart P—Event Data Recorders Phase-In Reporting Requirements

Sec.	
585.142	Scope
585.143	Purpose
585.144	Applicability
585.145	Definitions
585.146	Response to inquiries
585.147	Reporting requirements
585.148	Records

Subpart P—Event Data Recorders Phase-In Reporting Requirements

§ 585.142 Scope

This subpart establishes requirements for manufacturers of passenger cars, multipurpose passenger vehicles, trucks, and buses with a GVWR of 3,855 kg (8,500 pounds) or less and an unloaded vehicle weight of 2,495 kg (5,500 pounds) or less, except for walk-in van-type trucks or vehicles designed to be sold exclusively to the U.S. Postal Service, to submit a report per § 585.147, and maintain records related to the report according to § 585.148, concerning the number of such vehicles that meet the requirements of part 563, *Event data recorders* (49 CFR 563).

§ 585.143 Purpose

The purpose of these reporting requirements is to assist the National Highway Traffic Safety Administration in determining whether a manufacturer has complied with Part 563 (49 CFR 563).

§ 585.144 Applicability

This subpart applies to manufacturers of passenger cars, multipurpose passenger vehicles, trucks, and buses with a GVWR of 3,855 kg (8,500 pounds) or less and an unloaded vehicle weight of 2,495 kg (5,500 pounds) or less, except for walk-in van-type trucks or vehicles designed to be sold exclusively to the U.S. Postal Service, for which Part 563 applies. However, this subpart does not apply to vehicles

excluded by § 563.3 from the requirements of that standard.

§ 585.145 Definitions

(a) *Event data recorder (EDR)* is used as defined in 49 CFR 563.5.

§ 585.146 Response to inquiries

At any time during the production years ending August 31, 2029, August 31, 2030, August 31, 2031, and August 31, 2032, each manufacturer shall, upon request from the Office of Vehicle Safety Compliance, provide information identifying the vehicles (by make, model and vehicle identification number) that have been certified as complying with part 563 (49 CFR 563). The manufacturer's designation of a vehicle as a certified vehicle is irrevocable.

§ 585.147 Reporting requirements

(a) *General reporting requirements.* Within 60 days after the end of the production years ending August 31, 2029, August 31, 2030, August 31, 2031, and August 31, 2032, each manufacturer shall submit a report to the National Highway Traffic Safety Administration concerning its compliance with the event data recorder requirements of part 563 (49 CFR 563) for applicable vehicles produced in that year. Each report shall:

- (1) Identify the manufacturer;
- (2) State the full name, title, and address of the official responsible for preparing the report;
- (3) Identify the production year being reported on;
- (4) Contain a statement regarding whether or not the manufacturer complied with the event data recorder data element capture requirements of part 563 (49 CFR 563) for the period covered by the report and the basis for that statement;
- (5) Provide the information specified in paragraph (b) of this section;
- (6) Be written in the English language; and
- (7) Be submitted to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Ave. SE, West Building, Washington, DC 20590.

(b) *Report content*—(1) *Basis for phase-in production goals.* Each manufacturer must provide the number of passenger cars, multipurpose passenger vehicles, trucks, and buses with a GVWR of 3,855 kg (8,500

pounds) or less and an unloaded vehicle weight of 2,495 kg (5,500 pounds) or less, except for walk-in van-type trucks or vehicles designed to be sold exclusively to the U.S. Postal Service, manufactured for sale in the United States for each of the most recent three previous production years, or, at the manufacturer's option, for the most recently ended production year that are equipped with an EDR that meets the requirements in part 563. A new manufacturer that has not previously manufactured these vehicles for sale in the United States must submit a report at the end of the initial production year for the number of such vehicles manufactured during the initial production year.

(2) *Production.* Each manufacturer must report for the production year for which the report is filed: the number of passenger cars, multipurpose passenger vehicles, trucks, and buses with a GVWR of 3,855 kg (8,500 pounds) or less and an unloaded vehicle weight of 2,495 kg (5,500 pounds) or less, except for walk-in van-type trucks or vehicles designed to be sold exclusively to the U.S. Postal Service, that are equipped with an EDR and that do and do not meet § 563.7 (49 CFR 563.7).

(3) *Vehicles produced by more than one manufacturer.* Each manufacturer whose reporting of information is affected by one or more of the express written contracts permitted by § 563.7(b)(5) must:

- (i) Report the existence of each contract, including the names of all parties to the contract, and explain how the contract affects the report being submitted.
- (ii) Report the actual number of vehicles covered by each contract.

§ 585.148 Records

Each manufacturer must maintain records of the Vehicle Identification Number for each vehicle for which information is reported under § 585.147 until December 31, 2033.

Issued under authority delegated in 49 CFR 1.95. The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29A.

Jonathan Morrison,
Administrator.

[FR Doc. 2025–21506 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 90, No. 227
Friday, November 28, 2025

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.

CIVIL RIGHTS COLD CASE RECORDS REVIEW BOARD

[Agency Docket Number: CRCCRRB–2026–0002–N]

Notice of Formal Determination on Records Release

AGENCY: Civil Rights Cold Case Records Review Board.

ACTION: Notice.

SUMMARY: The Civil Rights Cold Case Records Review Board previously reviewed and made formal disclosure determinations on records related to civil rights cold case incident 2024–003–006 in which the National Archives and Records Administration (NARA) proposed postponements. NARA later proposed 8 additional postponements. On September 19, 2025, the Review Board determined that 408 pages in full and 10 pages in part should be publicly disclosed in the Civil Rights Cold Case Records Collection. By issuing this notice, the Review Board complies with the Civil Rights Cold Case Records Collection Act of 2018 that requires the Review Board to publish in the **Federal Register** its determinations on the

disclosure or postponement of records in the Collection no more than 14 days after the date of its decision.

FOR FURTHER INFORMATION CONTACT: Stephannie Oriabure, Chief of Staff, Civil Rights Cold Case Records Review Board, 1800 F Street NW, Washington, DC 20405, (771) 221–0014, *info@coldcaserecords.gov*.

SUPPLEMENTARY INFORMATION:

Incident identifier	Postponement identifier	Review board decision
2024–003–006	2025–NARA–03–0392 through 2025–NARA–03–0395	Approve.
2024–003–006	2025–NARA–03–0396	Reject.
2024–003–006	2025–NARA–03–0397	Approve.
2024–003–006	2025–NARA–03–0398	Approve with changes.
2024–003–006	2025–NARA–03–0399	Approve.

Authority: Public Law 115–426, 132 Stat. 5489 (44 U.S.C. 2107).

Dated: November 19, 2025.

Stephannie Oriabure,
Chief of Staff.

[FR Doc. 2025–21342 Filed 11–26–25; 8:45 am]

BILLING CODE 6820–SY–P

CIVIL RIGHTS COLD CASE RECORDS REVIEW BOARD

[Agency Docket Number: CRCCRRB–2026–0003–N]

Notice of Formal Determination on Records Release

AGENCY: Civil Rights Cold Case Records Review Board.

ACTION: Notice.

SUMMARY: The Civil Rights Cold Case Records Review Board previously reviewed and made formal disclosure determinations on records related to civil rights cold case incident 2024–003–041 in which the Department of Justice proposed postponements. The Department later proposed 6 additional postponements. On October 10, 2025, the Review Board determined that 63 pages in full and 43 pages in part produced by the Department of Justice should be publicly disclosed in the Civil Rights Cold Case Records Collection. By issuing this notice, the Review Board complies with the Civil Rights Cold Case Records Collection Act of 2018 that

requires the Review Board to publish in the **Federal Register** its determinations on the disclosure or postponement of records in the Collection no more than 14 days after the date of its decision.

FOR FURTHER INFORMATION CONTACT: Stephannie Oriabure, Chief of Staff, Civil Rights Cold Case Records Review Board, 1800 F Street NW, Washington, DC 20405, (771) 221–0014, *info@coldcaserecords.gov*.

SUPPLEMENTARY INFORMATION:

Incident identifier	Postponement identifier	Review board decision
2024–003–041	2024–DOJ–03–0643a	Reject.
2024–003–041	2024–DOJ–03–0649a	Reject.
2024–003–041	2024–DOJ–03–0649b	Reject.
2024–003–041	2024–DOJ–03–0650a	Reject.
2024–003–041	2024–DOJ–03–0650b	Reject.
2024–003–041	2024–DOJ–03–0715a	Reject.

Authority: Public Law 115–426, 132 Stat. 5489 (44 U.S.C. 2107).

Dated: October 23, 2025.

Stephannie Oriabure,
Chief of Staff.

[FR Doc. 2025–21344 Filed 11–26–25; 8:45 am]

BILLING CODE 6820–SY–P

CIVIL RIGHTS COLD CASE RECORDS REVIEW BOARD

[Agency Docket Number: CRCCRRB–2026–0001–N]

Notice of Formal Determination on Records Release

AGENCY: Civil Rights Cold Case Records Review Board.

ACTION: Notice.

SUMMARY: The Civil Rights Cold Case Records Review Board received 2,883 pages of records from the National Archives and Records Administration (NARA) and the Federal Bureau of Investigation (FBI) related to three civil rights cold case incidents to which the Review Board assigned the unique identifiers 2024–003–020, 2024–003–037, and 2024–003–039. The agencies proposed 65 postponements in the records. The FBI later withdrew 17 of the postponements the Bureau proposed after consultation with the Review Board. On September 12 and October 3, 2025, the Review Board approved 22 postponements and portions of 2 additional postponements, and determined that 2,866 pages in full and 17 pages in part should be publicly disclosed in the Civil Rights Cold Case Records Collection. The Review Board

is still coordinating its review of 18 proposed postponements with the agencies because of the sensitive nature of the information. This information is postponed until this coordination is complete and the Review Board can make a final disclosure decision. By issuing this notice, the Review Board complies with the Civil Rights Cold Case Records Collection Act of 2018 that requires the Review Board to publish in the **Federal Register** its determinations on the disclosure or postponement of records in the Collection no more than 14 days after the date of its decision.

FOR FURTHER INFORMATION CONTACT:

Stephannie Oriabure, Chief of Staff, Civil Rights Cold Case Records Review Board, 1800 F Street NW, Washington, DC 20405, (771) 221–0014, info@coldcaserecords.gov.

SUPPLEMENTARY INFORMATION:

Incident identifier	Postponement identifier	Review board decision
2024–003–020	2024–NARA–03–0103 through 2024–NARA–03–0106	Postponed while undergoing Board review.
2024–003–020	2024–NARA–03–0107 through 2024–NARA–03–0126	Approve.
2024–003–020	2024–NARA–03–0127 through 2024–NARA–03–0133	Postponed while undergoing Board review.
2024–003–020	2024–FBI–03–2838c and 2024–FBI–03–2838d	Withdrawn.
2024–003–020	2024–FBI–03–2839 through 2024–FBI–03–2844	Withdrawn.
2024–003–020	2024–FBI–03–2845	Approve with changes.
2024–003–020	2024–FBI–03–2846 through 2024–FBI–03–2851	Withdrawn.
2024–003–037	2025–NARA–03–0083 through 2025–NARA–03–0087	Postponed while undergoing Board review.
2024–003–039	2024–NARA–03–0086 through 2024–NARA–03–0088	Reject.
2024–003–039	2024–NARA–03–0089 and 2024–NARA–03–0090	Postponed while undergoing Board review.
2024–003–039	2024–NARA–03–0091 through 2024–NARA–03–0093	Reject.

Authority: Public Law 115–426, 132 Stat. 5489 (44 U.S.C. 2107).

Dated: September 30, 2025.

Stephannie Oriabure,
Chief of Staff.

[FR Doc. 2025–21343 Filed 11–26–25; 8:45 am]

BILLING CODE 6820–SY–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–320–2025]

Approval of Subzone Status; Elite Logistix, LLC; Rock Hill, South Carolina

On September 12, 2025, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the South Carolina State Ports Authority, grantee of FTZ 38, requesting subzone status subject to the existing activation limit of FTZ 38, on behalf of Elite Logistix, LLC, in Rock Hill, South Carolina.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the

Federal Register inviting public comment (90 FR 44799, September 17, 2025). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 38V was approved on November 25, 2025, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 38's 2,000-acre activation limit.

Dated: November 25, 2025.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2025–21563 Filed 11–26–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–326–2025]

Approval of Subzone Status; Coroplast Tape Corporation; Rock Hill, South Carolina

On September 17, 2025, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the South Carolina State Ports Authority, grantee of FTZ 38, requesting subzone status subject to the existing activation limit of FTZ 38, on behalf of Coroplast Tape Corporation, in Rock Hill, South Carolina.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (90 FR 45172, September 19, 2025). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 38W was approved on November 25, 2025, subject to the FTZ

Act and the Board's regulations, including section 400.13, and further subject to FTZ 38's 2,000-acre activation limit.

Dated: November 25, 2025.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2025–21564 Filed 11–26–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2025–0479]

Grant of Interim Extension of the Term of U.S. Patent No. 8,785,125; the Aptima® HPV Assay With the Panther® System

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 8,785,125 ('125 patent).

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–0909 or ali.salimi@uspto.gov; or Andrea S. Grossman, Legal Advisor at (571) 270–3314 or email andrea.grossman@uspto.gov.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 generally provides that the term of a patent may be extended for a period of up to five years, if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period (RRP) is reasonably expected to extend beyond the expiration date of the patent.

On November 20, 2025, Gen-Probe Incorporated, the patent owner of record of the '125 patent, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of the '125 patent. The '125 patent claims the medical device known by tradename Aptima® HPV Assay with the Panther® System and a method of using this medical device. The application indicates that the approval phase “continues” for the regulatory period, as described in 35 U.S.C. 156(g)(1)(B)(ii),

for Premarket Approval (PMA) 100042/S038 for the Aptima® HPV Assay with the Panther® System and is ongoing before the Food and Drug Administration for permission to market and use the product commercially.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the '125 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it appears reasonable to expect the approval phase of the RRP to continue beyond the expiration date of the patent, *i.e.*, December 8, 2025, interim extension of the '125 patent's term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 8,785,125 is granted for a period of one year from the original expiration date of the patent.

Charles Kim,

Deputy Commissioner for Patents, United States Patent and Trademark Office.

[FR Doc. 2025–21411 Filed 11–26–25; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2025–0014]

Revised Inventorship Guidance for AI-Assisted Inventions

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Examination guidance.

SUMMARY: The United States Patent and Trademark Office (USPTO) had issued inventorship guidance for AI-assisted inventions on February 13, 2024.¹ The USPTO hereby rescinds the previously published Inventorship Guidance for AI-Assisted Inventions and replaces it with the guidance below.

FOR FURTHER INFORMATION CONTACT:

Christian Hannon, Senior Patent Attorney, at 571–272–7385; or Courtney Stopp, Patent Attorney, at 571–270–5559, both with the Office of Policy and International Affairs.

SUPPLEMENTARY INFORMATION:

I. Purpose

This notice provides further guidance on the proper legal standard for determining inventorship in patent applications for AI-assisted inventions.

¹ Inventorship Guidance for AI-Assisted Inventions, 89 FR 10043 (Feb. 13, 2024).

II. Rescission of Prior Guidance

The guidance issued on February 13, 2024, titled “Inventorship Guidance for AI-Assisted Inventions” is rescinded in its entirety. The approach set forth in that guidance, which relied on the application of the *Pannu*² factors to AI-assisted inventions, is withdrawn. The *Pannu* factors only apply when determining whether multiple natural persons qualify as joint inventors.³ *Pannu* is inapplicable when only one natural person is involved in developing an invention with AI assistance because AI systems are not persons and therefore cannot be “joint inventors” so there is no joint inventorship question to analyze.⁴

III. Governing Legal Standards

The same legal standard for determining inventorship applies to all inventions, regardless of whether AI systems were used in the inventive process.⁵ There is no separate or modified standard for AI-assisted inventions.

The Federal Circuit has held that AI cannot be named as an inventor on a patent application (or issued patent) and that only natural persons can be inventors.⁶ Artificial intelligence systems, regardless of their sophistication, cannot be named as inventors or joint inventors on a patent application as they are not natural persons.⁷

The Federal Circuit has centered its inventorship inquiry around “conception,” characterizing conception as “the touchstone of inventorship.”⁸ Conception is “the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”⁹ Conception is complete when “the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan.”¹⁰

² *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998).

³ *Id.*

⁴ See *Thaler v. Vidal*, 43 F.4th 1207, 1212 (Fed. Cir. 2022) (holding that only a natural person(s) may be listed as an inventor(s)).

⁵ See 35 U.S.C. 115(b)(2) (2024) (providing the standard for naming inventorship across all types of utility patent applications).

⁶ *Thaler*, 43 F.4th at 1212.

⁷ See *id.*

⁸ *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (citing *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994)).

⁹ *Id.* (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson on Patents 532 (1890))).

¹⁰ *Id.*

Determining inventorship is highly fact intensive.¹¹ The question is whether the natural person possessed knowledge of all the limitations of the claimed invention such that it is so “clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.”¹² Analysis of conception turns on the ability of an inventor to describe an invention with particularity.¹³ Absent such a description, an inventor cannot objectively prove possession of a complete mental picture of the invention at a later time.¹⁴

IV. Inventorship Guidance for AI-Assisted Inventions

Generally, the USPTO presumes those inventors named on the application data sheet or oath/declaration are the actual inventor or joint inventors of the application.¹⁵ A rejection under 35 U.S.C. 101 and 115, or other appropriate action, should be made for all claims in any application that lists an AI system or other non-natural person as an inventor or joint inventor.

AI systems, including generative AI and other computational models, are instruments used by human inventors. They are analogous to laboratory equipment, computer software, research databases, or any other tool that assists in the inventive process. As the case law establishes, inventors may “use the services, ideas, and aid of others” without those sources becoming co-inventors.¹⁶ The same principle applies to AI systems: they may provide services and generate ideas, but they remain tools used by the human inventor who conceived the claimed invention. When one natural person is

involved in creating an invention with the assistance of AI, the inquiry is whether that person conceived the invention under the traditional conception standard set forth above in Section III.

When multiple natural persons are involved in creating an invention with AI assistance, the traditional joint inventorship principles apply, including the *Pannu* factors to determine whether each person qualifies as a joint inventor.¹⁷ Each purported inventor must “(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.”¹⁸ The fact that AI tools were used in the development process does not change the joint inventorship analysis among the human contributors.

V. Applicability of This Guidance to Design and Plant Patent Applications and Patents

35 U.S.C. 171 provides that a patent for a design may be obtained by “[w]hoever invents any new, original, and ornamental design for an article of manufacture” and that the provisions related to utility patents are applicable to design patents, except as otherwise provided (e.g., in 35 U.S.C. 172–173).¹⁹ The Federal Circuit has interpreted 35 U.S.C. 171 such that the inventorship inquiry is the same for a design patent and a utility patent.²⁰

35 U.S.C. 161 provides that a plant patent may be obtained by “[w]hoever invents or discovers and asexually reproduces” a distinct and new variety of plant.²¹ 35 U.S.C. 161 limits patent protection to plants “that were created as a result of plant breeding or other agricultural and horticultural efforts and that were created by the inventor” (emphasis in original).²² That is, to be entitled to patent protection, the inventor of a plant must have contributed to the creation of the plant in addition to having appreciated its

uniqueness and asexually reproduced it.²³ This is true for new and distinct plant varieties invented with the assistance of AI.

Therefore, this guidance regarding AI-assisted inventions applies not only to utility patents and patent applications but also to design and plant patents and patent applications.

VI. Benefit/Priority Claims to Prior-Filed Applications

Applications and patents claiming the benefit of, or priority to, a prior application filed in the United States or a foreign country under 35 U.S.C. 119, 120, 121, 365, or 386 must name the same inventor or have at least one joint inventor in common with the prior-filed application.²⁴ For all applications and patents, including those that cover AI-assisted inventions, the prior-filed application and the United States application or patent claiming the benefit of, or priority to, the prior-filed application must name the same natural person as the inventor, or have at least one joint inventor who is a natural person in common. Therefore, a priority claim to a foreign application that names an AI tool as the sole inventor will not be accepted. This policy also applies to U.S. patent applications and patents claiming priority to foreign applications that allow the naming of non-natural persons as joint inventors. For a U.S. application claiming priority to a foreign application that names both a natural person(s) and a non-natural person as a joint inventor, the application data sheet accompanying the application filed in the United States must list only the natural person(s) identified as the inventor(s), including one in common with the foreign application. Similarly, for an application entering the national stage under 35 U.S.C. 371 where the international application indicates a joint inventor that is not a natural person, applicants can comply with the U.S. inventorship requirement by naming the natural person(s) identified as the inventor(s) in an application data sheet accompanying the initial submission under 35 U.S.C. 371.²⁵

John A. Squires,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2025–21457 Filed 11–26–25; 8:45 am]

BILLING CODE 3510–16–P

²³ *Id.* at 1348.

²⁴ See MPEP 213.02 (subsection II), 211.01, 1895, 2920.05(e).

²⁵ See 37 CFR 1.76; MPEP 1893.01(e).

¹¹ *In re Jolley*, 308 F.3d 1317, 1323 (Fed. Cir. 2002).

¹² *Burroughs Wellcome Co.*, 40 F.3d at 1228 (citing *Sewall*, 21 F.3d at 415).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See MPEP 2157; see also MPEP 602.01 (“The inventorship of a nonprovisional application under 35 U.S.C. 111(a) is the inventor or joint inventors set forth in the application data sheet in accordance with [37 CFR] § 1.76 filed before or concurrently with the inventor’s oath or declaration.”).

¹⁶ *Shatterproof Glass Corp. v. Libby-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir. 1985) (quoting *Hobbs v. United States Atomic Energy Commission*, 451 F.2d 849, 864 (5th Cir. 1971)); see also *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 981 (Fed. Cir. 1997) (quoting *O’Reilly v. Morse*, 56 U.S. 62, 111 (1853) (“it can make no difference [. . .] whether [the inventor] derives his information from books, or from conversation with men skilled in the science.”) [. . .] “the fact that Morse sought and obtained the necessary information and counsel from the best sources, and acted upon it, neither impairs his rights as an inventor, nor detracts from his merits.”)).

¹⁷ *Pannu*, 155 F.3d at 1351.

¹⁸ *Id.*

¹⁹ 35 U.S.C. 171 (2024).

²⁰ *Hoop v. Hoop*, 279 F.3d 1004, 1007 (Fed. Cir. 2002) (“We apply the same standard of inventorship to design patents that we require for utility patents.”) (citing *In re Rouso*, 222 F.2d 729, 731 (CCPA 1955)).

²¹ 35 U.S.C. 161 (2024).

²² *In re Beineke*, 690 F.3d 1344, 1352 (Fed. Cir. 2012).

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action deletes products and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Date added to and deleted from the Procurement List: December 21, 2025.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington DC, 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 489-1322, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Deletions

On September 11, 2025 (90 FR 44051) and September 25, 2025 (90 FR 46186), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51-2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501-8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 8520-01-522-0831—Refill, Soap, Antibacterial, 2000 mL

Authorized Source of Supply: Travis Association for the Blind, Austin, TX
Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI

NSN(s)—Product Name(s): 7210-00-682-6503—Mattress, Foam, Polyurethane, Cotton Ticking, Blue Stripes, 75" L x 38" W x 4" H

Authorized Source of Supply: Lions Volunteer Blind Industries, Inc., Morristown, TN

Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI

NSN(s)—Product Name(s):

8465-01-656-1719—Belt, Individual Equipment, LC-1, Olive Drab, No U.S. Markings, Medium

8465-01-656-1721—Belt, Individual Equipment, LC-1, Olive Drab, No U.S. Markings, Large

Authorized Source of Supply: Mississippi Industries for the Blind, Inc., Jackson, MS

Authorized Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC

Contracting Activity: DLA TROOP SUPPORT

NSN(s)—Product Name(s):

8415-00-782-2948—Trousers, Cold Weather Water Repellent, Army, Green, XSR

8415-01-099-7853—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, XSR

8415-01-099-7854—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, SR

8415-01-099-7855—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, SR

8415-01-099-7856—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, SL

8415-01-099-7857—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, MS

8415-01-099-7858—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, MR

8415-01-099-7859—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, ML

8415-01-099-7860—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, LR

8415-01-099-7861—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, LL

8415-01-099-7862—Trousers, Cold Weather Water Repellent, Army, Printed Black, Brown and Green Camouflage, XLL

8415-01-100-0977—Trousers, Cold Weather Water Repellent, Army, Printed

Black, Brown and Green Camouflage, XLR

Authorized Source of Supply: Goodwill Industries of South Florida, Inc., Miami, FL

Contracting Activity: DLA TROOP SUPPORT

NSN(s)—Product Name(s): 8465-01-012-9174—Clipboard, Pilots

Authorized Source of Supply: Human Technologies Corporation, Utica, NY

Contracting Activity: DLA TROOP SUPPORT

NSN(s)—Product Name(s):

9905-01-661-2144—Flag, Marking, 2-1/2" x 3-1/2", 21" Staff, Fluorescent Pink

9905-01-661-2145—Flag, Marking, 2-1/2" x 3-1/2", 21" Staff, Orange

9905-01-661-2149—Flag, Marking, 2-1/2" x 3-1/2", 21" Staff, Orange

9905-01-661-2153—Flag, Marking, 2-1/2" x 3-1/2", 21" Staff, Yellow

Authorized Source of Supply: West Texas Lighthouse for the Blind, San Angelo, TX

Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI

NSN(s)—Product Name(s): 8465-01-012-9174—Clipboard, Pilots

Authorized Source of Supply: Human Technologies Corporation, Utica, NY

Contracting Activity: DLA TROOP SUPPORT

NSN(s)—Product Name(s):

7510-01-484-1745—Binder, Round Ring, Polyethylene, Flexible, Blue, 2" Capacity, Letter Size

7510-01-511-4320—Binder, Round Ring, Pockets, Gray, 3" Capacity, Letter Size

7510-01-519-4363—Binder, Round Ring, Clear Overlay, Pockets, Green, 1 1/2" Capacity, Letter Size

Authorized Source of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2)

Contracting Activity: DEPARTMENT OF VETERANS AFFAIRS, STRATEGIC ACQUISITION CENTER

NSN(s)—Product Name(s):

7045-01-568-4203—USB Flip Drive, Water Resistant, Silver/Black, 2GB

7045-01-568-4204—USB Flip Drive, Water Resistant, Silver/Black, 4GB

7045-01-568-4208—USB Flash Drive, 256-Bit SES Encryption, Water Resistant, Silver/Black, 2GB

7045-01-568-4209—USB Flash Drive, 256-Bit SES Encryption, Water Resistant, Silver/Black, 4GB

Authorized Source of Supply: North Central Sight Services, Inc., Williamsport, PA

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2)

NSN(s)—Product Name(s):

7045-01-406-5391—Compact Disc, Recordable, Gold, BX/25

7045-01-429-3462—Compact Disc, Recordable, Gold, Sleeves and Mailers

Authorized Source of Supply: North Central Sight Services, Inc., Williamsport, PA

Contracting Activity: DLA TROOP SUPPORT

Service(s)

Service Type: Messenger Services

Mandatory for: DHS CBP, Area Port St. Thomas, USVI

Contracting Activity: U.S. CUSTOMS AND

BORDER PROTECTION, BORDER
ENFORCEMENT CTR DIV

Service Type: Mailroom Operation

Mandatory for: U.S. Customs Indianapolis

Center: 6026 Lakeside Boulevard

Contracting Activity: U.S. CUSTOMS AND

BORDER PROTECTION, ADMIN

FACILITIES TRAINING CTR DIV

Service Type: Base Supply Center

Mandatory for: Forbes Field Air National

Guard Base, Topeka, KS

Contracting Activity: DEPT OF THE ARMY,

W7M9 USPFO ACTIVITY KSANG 190

Service Type: BSC/IEE/Hazmat

Mandatory for: Forbes Field, KS

Contracting Activity: DOD/DEPARTMENT

OF THE AIR FORCE

Service Type: Custodial Services

Mandatory for: USMA, Child Development

Center, West Point, NY

Contracting Activity: DEPT OF THE ARMY,

W6QM MICC—WEST POINT

Service Type: Administrative Services

Mandatory for: US Customs and Border

Protection, Callexico SENTRI Enrollment

Center, Area Port of Callexico, Callexico,

CA

Contracting Activity: U.S. CUSTOMS AND

BORDER PROTECTION, BORDER

ENFORCEMENT CTR DIV

Service Type: Janitorial/Custodial

U.S. Army Reserve Center: 4301 Goodfellow

Boulevard, Center #3

Mandatory for: U.S. Army Reserve Center:

4301 Goodfellow Boulevard, Center #3

Contracting Activity: DEPT OF THE ARMY,

W6QM MICC FT MCCOY (RC)

Service Type: Custodial

Mandatory for: FAA, EWR TSS Room, North

Cargo Bldg 157, Liberty International

Airport, Newark, NJ

Contracting Activity: FEDERAL AVIATION

ADMINISTRATION, 697DCK

REGIONAL ACQUISITIONS SVCS

Service Type: Embroidery of USAF Service

Name Tapes & Emboss

Mandatory for: Lackland Air Force Base

Contracting Activity: DEPT OF THE AIR

FORCE, FA7014 AFDW PK

Service Type: Janitorial/Custodial

Mandatory for: GSA PBS Region 5, Eau Claire

Federal Building and US Courthouse,

Eau Claire, WI

Contracting Activity: GENERAL SERVICES

ADMINISTRATION, PBS R5

Service Type: Laundry/Dry Cleaning

Mandatory for: US Army, Fort Johnson, 2038

9th Street Bldg 1352, Fort Johnson, LA

Contracting Activity: DEPT OF THE ARMY,

W6QM MICC—FT JOHNSON

Service Type: Admin Services for FPS in San

Francisco and Los Angeles

Mandatory for: DHS, FPS, Region 9, Federal

Protective Service, Reno, NV

Contracting Activity: DEPT OF HOMELAND

SECURITY, FPS WEST CCG

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2025–21466 Filed 11–26–25; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and delete product(s) and service(s) previously furnished by such agencies.

DATES: Comments must be received on or before: December 27, 2025.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington DC, 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 489–1322, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

Product(s)

In accordance with 41 CFR 51–2.4(b), Government personnel within the contracting activity have identified this as a product requirement not applicable to other Federal entities and has requested the Committee consider granting a purchase or distribution preference if the product is added to the Procurement List. *See* 71 FR 69536 (Dec. 1, 2006). If the Committee grants this request, the products will not be available through the U.S. AbilityOne Commission's Commercial Distribution Program. The Committee will consider this request along with relevant comments received from interested parties.

The following product(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

NSN(s)—Product Name(s):

810012201N—Package Filler, Cushioning, Bubble, Roll, Perforated, 12' x 175"

Authorized Source of Supply:

Alphapointe, Kansas City, MO

Mandatory For: Total Government Requirement

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2 1095–01–598–4343—Combat Knife, Mini, Out the Front (OTF)

Authorized Source of Supply: DePaul Industries, Portland, OR

Mandatory For: DEPARTMENT OF DEFENSE

Contracting Activity: DLA LAND AND MARITIME, LAND SUPPLIER OPERATIONS SMS

Service(s)

In accordance with 41 CFR 51–5.3(b), the Committee intends to add this services requirement to the Procurement List as a mandatory purchase only for the contracting activity listed at location listed with the proposed qualified nonprofit agency as the authorized source of supply. Prior to adding the service to the Procurement List, the Committee will consider other pertinent information, including information from Government personnel and relevant comments from interested parties regarding the Committee's intent to geographically limit this services requirement.

Service Type: Tactical Fleet Operator Support

Mandatory for: US Army, Directorate of Training Sustainment, Fort Benning, Fort Benning, GA

Contracting Activity: DEPT OF THE ARMY, W6QM MICC—FT MOORE

Authorized Source of Supply: Brevard Achievement Center, Inc., Rockledge, FL

Deletions

The following product(s) and service(s) are proposed for deletion to the Procurement List:

Product(s)

NSN(s)—Product Name(s):

8415–01–092–7514—Cover, PASGT

Helmet, Woodland Camouflage, XS/S

8415–01–092–7515—Cover, PASGT

Helmet, Woodland Camouflage, M/L

8415–01–303–8945—Cover, PASGT

Helmet, Woodland Camouflage, X–LG

8415–01–521–8357—Cover, Advanced

Combat Helmet, No Comm Flap,

Universal Camouflage, S/M

8415–01–521–8360—Cover, Advanced

Combat Helmet, No Comm Flap,

Universal Camouflage, L/XL

8415–01–521–8806—Cover, Advanced

Combat Helmet, with Comm Flap,

Universal Camouflage, S/M

8415–01–521–8808—Cover, Advanced

Combat Helmet, with Comm Flap,

Universal Camouflage, L/XL

8415–01–591–5907—Cover, Enhanced

Combat Helmet, Universal Camouflage

Pattern, S/M

8415-01-591-5918—Cover, Enhanced
Combat Helmet, Universal Camouflage
Pattern, L/XL

8415-01-591-5946—Cover, Enhanced
Combat Helmet, Universal Camouflage
Pattern, XXL

Authorized Source of Supply: Alabama
Industries for the Blind, Talladega, AL
Authorized Source of Supply: Lions Services,
Inc., Charlotte, NC

Authorized Source of Supply: Industries of
the Blind, Inc, Greensboro, NC

Authorized Source of Supply: Lions
Volunteer Blind Industries, Inc.,
Morristown, TN

Authorized Source of Supply: The
Lighthouse for the Blind in New Orleans,
Inc., New Orleans, LA

Authorized Source of Supply: Blind
Industries & Services of Maryland,
Baltimore, MD

Authorized Source of Supply: Mississippi
Industries for the Blind (Inc), Jackson,
MS

Authorized Source of Supply: LC Industries,
Inc., Durham, NC

Authorized Source of Supply: Winston-Salem
Industries for the Blind, Inc, Winston-
Salem, NC

Authorized Source of Supply: Mount Rogers
Community Services Board, Wytheville,
VA

Mandatory For: DEPARTMENT OF DEFENSE
Contracting Activity: DEFENSE LOGISTICS
AGENCY, DLA TROOP SUPPORT

Contracting Activity: DEPT OF THE ARMY,
W6QK ACC-APG NATICK

Service(s)

Service Type: Janitorial Custodial
Mandatory for GSA: Courthouses, Portland
OR

Contracting Activity: GENERAL SERVICES
ADMINISTRATION, PUBLIC
BUILDINGS SERVICE, PBS R10

Service Type: Grounds Maintenance, Guard
Services, Alarm Monitoring

Mandatory for GSA: Fort Sam Houston and
Camp Bullis Reserve Centers: Building
1610 (2010 Harry Wurzbach Highway),
Robert Gray Army Airfield (RGAAF): III
Corps and Fort Hood Army Airfield and
U.S. Army Reserve Center: 1920 Harry
Wurzbach Highway

Contracting Activity: DEPT OF THE ARMY,
W40M RHCO-ATLANTIC USAHCA

Service Type: Janitorial/Custodial
Mandatory for GSA: US Office of Personnel
Management, Federal Executive
Institute, Charlottesville, VA

Contracting Activity: OFFICE OF
PERSONNEL MANAGEMENT, OPM DC
CENTRAL OFFICE CONTRACTING

Service Type: Document Management

Mandatory for GSA: USDA Forest Service,
Pacific Northwest Region, Region 6, &
the Pacific Northwest Research
Station, 1220 SW 3rd Avenue, Portland,
OR

Contracting Activity: DEPT OF
AGRICULTURE, FOREST SERVICE,
NORTHWEST OREGON CONTRACTING

AREA

Michael R. Jurkowski,
Director, Business Operations.

[FR Doc. 2025-21465 Filed 11-26-25; 8:45 am]

BILLING CODE 6353-01-P

COMMODITY FUTURES TRADING COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Commodity Futures Trading
Commission.

ACTION: Notice of a modified system of
records.

SUMMARY: In accordance with the
Privacy Act of 1974 and in compliance
with Executive Order 14249, *Protecting
America's Bank Account Against Fraud,
Waste, and Abuse*, and Office of
Management and Budget Memorandum
M-25-32, *Preventing Improper
Payments and Protecting Privacy
Through Do Not Pay*, the Commodity
Futures Trading Commission (CFTC or
Commission) is modifying four Privacy
Act systems of records by adding a new
routine use to permit the disclosure of
records to the Department of the
Treasury. In addition, in accordance
with Office of Management and Budget
Memorandum M-17-12, *Preparing for
and Responding to a Breach of
Personally Identifiable Information*, the
CFTC is adding routine uses to three of
those systems of records to permit the
disclosure of records in response to a
breach. These modified systems of
records will be included in the CFTC's
inventory of record systems.

DATES: These modified systems of
records are effective December 29, 2025.
Please submit comments on or before
December 29, 2025.

ADDRESSES: You may submit comments,
identified as pertaining to PA Routine
Uses, by any of the following methods:

- *CFTC Comments Portal:* <https://comments.cftc.gov>. Select the "Submit
Comments" link for this notice and
follow the instructions on the Public
Comment Form.

- *Mail:* Send to Christopher
Kirkpatrick, Secretary of the
Commission, Commodity Futures
Trading Commission, Three Lafayette
Centre, 1155 21st Street NW,
Washington, DC 20581.

- *Hand Delivery/Courier:* Follow the
same instructions as for Mail, above.

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

All comments must be submitted in
English, or if not, be accompanied by an
English translation. Comments will be
posted as received to <https://comments.cftc.gov>. You should submit
only information that you wish to make
available publicly.

The Commission reserves the right,
but shall have no obligation, to review,
pre-screen, filter, redact, refuse, or
remove any or all of a submission from
<https://comments.cftc.gov> that it may
deem to be inappropriate for
publication, such as obscene language.
All submissions that have been redacted
or removed that contain comments on
the merits of this notice will be retained
in the comment file and will be
considered as required under all
applicable laws and may be accessible
under the Freedom of Information Act.

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

SUPPLEMENTARY INFORMATION: In
accordance with the Privacy Act of 1974
and in compliance with Executive Order
14249, *Protecting America's Bank
Account Against Fraud, Waste, and
Abuse* (E.O. 14249), and Office of
Management and Budget Memorandum
M-25-32, *Preventing Improper
Payments and Protecting Privacy
Through Do Not Pay* (OMB M-25-32),
the Commodity Futures Trading
Commission (CFTC or Commission) is
modifying four Privacy Act systems of
records by adding a new routine use to
permit the disclosure of records to the
Department of the Treasury to review
payments through the Do Not Pay
Working System.

A "routine use" means, with respect
to the disclosure of a Privacy Act record,
the use of such record for a purpose
which is compatible with the purpose
for which it is collected." 5 U.S.C.
552a(a)(7). All agency systems of
records must have a system of records
notice (SORN) published in the **Federal
Register** and the SORN must describe
"each routine use of the records
contained in the system, including the
categories of users and the purposes of
such use." 5 U.S.C. 552a(e)(4)(D).

E.O. 14249 promotes financial
integrity by enabling the Department of
the Treasury to more easily conduct
improper payment and fraud prevention
screening prior to disbursing funds on
behalf of agencies" It requires agencies
to review and modify, as applicable,
their relevant system of records notices

under the Privacy Act of 1974 to include a “routine use” that allows for the disclosure of records to the Department of the Treasury for the purposes of identifying, preventing, or recouping fraud and improper payments, to the extent permissible by law.

The Office of Management and Budget, in OMB M–25–32, issued guidance concerning the routine use provisions in E.O. 14249. OMB M–25–32 requires agencies, in accordance with the Executive Order, to 1. identify which of their systems of records maintain information about applicants for, or recipients of, Federal funds that agencies use to make eligibility determinations for payments to beneficiaries, award and loan recipients, vendors, contractors, and other payees; 2. determine which of those systems of records maintain information whose disclosure to Treasury would be relevant and necessary for identifying, preventing, or recouping improper payments by reviewing payment and award eligibility through the Do Not Pay Working System; and 3. report to OMB and Congress in accordance with OMB Circular No. A–108 any proposal(s) to add the following routine use to the agency’s SORN(s) or to modify an existing routine use in the agency’s SORN(s) so that it conforms to the following routine use:

To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purpose of identifying, preventing, or recouping improper payment to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

The Commission has reviewed its SORNs and determined, in accordance with the mandate in E.O. 14249 and the guidance in M–25–32, to modify four of the CFTC SORNs to include the required routine use. These are:

- CFTC–5 Employee Personnel, Payroll, Time and Attendance
- CFTC–6 Employee Travel and Transportation Records
- CFTC–49 Whistleblower Records
- CFTC–51 Contractors and Consultants

In addition to adding the required routine use for disclosure to the Department of the Treasury to the above-referenced SORNs, the Commission has also determined to add two additional routine uses to permit disclosure of records in the context of a breach to three of those SORNs:

- CFTC–5 Employee Personnel, Payroll, Time and Attendance
 - CFTC–6 Employee Travel and Transportation Records
 - CFTC–49 Whistleblower Records
- Office of Management and Budget Memorandum M–17–12, *Preparing for and Responding to a Breach of Personally Identifiable Information*, (OMB M–17–12) sets forth the policy for Federal agencies to prepare for and respond to a breach of personally identifiable information (PII). It established two model routine uses, one permitting the disclosure of information related to breaches of an agency’s own records, and the second permitting the disclosure of agency records to assist other agencies in their efforts to respond to a breach. To date, the Commission has been adding these routine uses to individual SORNs when they otherwise require a modification, relying until those updates are in place on the Commission’s blanket routine use 19, which closely parallels the first of OMB M–17–12’s model routine uses. See 76 FR 5974. To that end, the Commission is deleting the reference to blanket routine use 19 in these three SORNs and including the following routine uses from OMB M–17–12:

To appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records, (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (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 Commission’s efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

To another Federal agency or Federal entity, when the Commission 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.

Finally, the Commission is making minor administrative edits to the System Location and System Manager sections of all four SORNs to address organizational changes within the Commission since they were last published.

These modified systems of records will be included in the CFTC’s inventory of record systems and, in

accordance with 5 U.S.C. 552a(r), the CFTC has provided a report of these modified systems of records to the Office of Management and Budget and to Congress.

CFTC–5

SYSTEM NAME AND NUMBER:

Employee Personnel, Payroll, Time and Attendance, CFTC–5.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Division of Administration, Human Resources Branch, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581, and at the Commission’s payroll processor, Department of Agriculture’s National Finance Center, New Orleans, LA.

SYSTEM MANAGER(S):

Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

* * * * *

e. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purpose of identifying, preventing, or recouping improper payment to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

f. To appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records, (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (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 Commission’s efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

g. To another Federal agency or Federal entity, when the Commission

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.

Information in this system may also be disclosed in accordance with blanket routine uses 1–18, available at 76 FR 5974 (Feb. 2, 2011), and on the Commission's website, <https://www.cftc.gov/privacy>.

HISTORY:

76 FR 6974 (Feb. 2, 2011), 81 FR 67327 (Sept. 30, 2016)

CFTC–6

SYSTEM NAME AND NUMBER:

Employee Travel and Transportation Records, CFTC–6.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Employee travel records are part of the E2 Solutions TAVS system operated by CW Government Travel located in Arlington, VA. Access to these records is through Office of Financial Management, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. The transit subsidy system is located in the Office of Management Operations, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SYSTEM MANAGER(S):

Deputy Director for Accounting and Financial Systems and Network Manager (travel and transportation records) and Director, Office of Management Operations (transit subsidy records), Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with blanket routine uses numbered 1 through 18 that are published in the **Federal Register** at 76 FR 5974 (Feb. 2, 2011). In addition, information in this system may be disclosed as follows:

a. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purpose of identifying, preventing, or recouping improper payment to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

b. To appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records, (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (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 Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

c. To another Federal agency or Federal entity, when the Commission 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.

HISTORY:

76 FR 5974 (Feb. 2, 2011)

CFTC–49

SYSTEM NAME AND NUMBER:

Whistleblower Records, CFTC–49.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Whistleblower Office, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SYSTEM MANAGER(S):

Senior Attorney Advisor, Whistleblower Office, Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Information in this system may be disclosed in accordance with blanket routine uses numbered 1 through 18 that are published in the **Federal Register** at 76 FR 5974 (Feb. 2, 2011). In addition, information in this system may be disclosed as follows:

a. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purpose of identifying, preventing, or recouping improper payment to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

b. To appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records, (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (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 Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

c. To another Federal agency or Federal entity, when the Commission 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.

HISTORY:

77 FR 41378 (July 13, 2012)

CFTC–51

SYSTEM NAME AND NUMBER:

Contractors and Consultants, CFTC–51.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Division of Administration, Business and Operations Branch, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 2058, and the Department of Transportation Enterprise Service Center, Oklahoma City, Oklahoma.

SYSTEM MANAGER(S):

Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

* * * * *

f. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purpose of identifying, preventing, or recouping improper payment to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

HISTORY:

83 FR 5997 (Feb. 12, 2018).

Issued in Washington, DC, on November 25, 2025, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2025–21510 Filed 11–26–25; 8:45 am]

BILLING CODE 6351–01–P

CONSUMER FINANCIAL PROTECTION BUREAU

[Docket No. CFPB–2025–0042]

Agency Information Collection Activities: Comment Request

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (CFPB or Bureau) is requesting to extend the Office of Management and Budget's (OMB's) approval for an existing information collection titled "Consumer Response Intake Form" approved under OMB Control Number 3170–0011.

DATES: Written comments are encouraged and must be received on or before January 27, 2026 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Email:* CFPB_PRA@cfpb.gov. Include Docket No. CFPB–2025–0042 in the subject line of the email.

- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552. Because paper mail in the Washington, DC area and at the CFPB is subject to delay, commenters are encouraged to submit comments electronically.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435–7278, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Consumer Response Intake Form.

OMB Control Number: 3170–0011.

Type of Review: Extension of a currently approved information collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 6,000,000.

Estimated Total Annual Burden Hours: 1,123,334.

Abstract: The Consumer Response Intake Form is designed to aid consumers in the submission of complaints, inquiries, and feedback and to help the Bureau fulfill its statutory requirements. Consumers (also referred to as respondents) will be able to complete and submit information through the Intake Form electronically on the Bureau's website. Alternatively, respondents may request that the Bureau mail a paper copy of the Intake Form and then mail it back to the

Bureau or call to submit a complaint by telephone. The questions within the Intake Form prompt respondents for a description of, and key facts about, the complaint at issue, the desired resolution, contact and account information, information about the company they are submitting a complaint about, and previous action taken to attempt to resolve the complaint.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the CFPB, including whether the information will have practical utility; (b) The accuracy of the CFPB's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2025–21451 Filed 11–26–25; 8:45 am]

BILLING CODE 4810–AM–P

CONSUMER FINANCIAL PROTECTION BUREAU

[Docket No. CFPB–2025–0041]

Agency Information Collection Activities: Comment Request

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (CFPB or Bureau) requests the Office of Management and Budget's (OMB's) extension of the existing information collection titled "Consumer Complaint Intake System Company Portal Boarding Form" approved under OMB Number 3170–0054.

DATES: Written comments are encouraged and must be received on or before December 29, 2025 to be assured of consideration.

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. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (304) 481–5511, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Consumer Complaint Intake System Company Portal Boarding Form.

OMB Control Number: 3170–0054.

Type of Review: Extension of a currently approved information collection.

Affected Public: Private sector.

Estimated Number of Respondents: 400.

Estimated Total Annual Burden Hours: 85.

Abstract: Section 1013(b)(3)(A) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, requires the CFPB to “facilitate the centralized collection of, monitoring of, and response to consumer complaints regarding consumer financial products or services.”¹ In furtherance of its statutory mandates related to consumer complaints, the CFPB utilizes a Consumer Complaint Intake System Company Portal Boarding Form (Boarding Form) to sign up companies for access to the secure, web-based Company Portal (Company Portal). The Company Portal allows companies to view and respond to complaints submitted to the CFPB, supports the efficient routing of consumer complaints to companies, and enables a

timely and secure response by companies to the CFPB and consumers.²

Request for Comments: The CFPB published a 60-day **Federal Register** notice on May 22, 2025 (90 FR 21905) under Docket Number: CFPB–2025–0027. The CFPB is publishing this notice and soliciting comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the CFPB, including whether the information will have practical utility; (b) The accuracy of the CFPB’s estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2025–21453 Filed 11–26–25; 8:45 am]

BILLING CODE 4810–AM–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2017–0044]

Agency Information Collection Activities; Extension of Collection; Comment Request; Safety Standard for Clothing Storage Units

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Consumer Product Safety Commission (CPSC or Commission) requests comments on a proposed extension of approval of information collection requirements associated with the Safety Standard for Clothing Storage Units. The Office of Management and Budget (OMB) previously approved the

collection of information under control number 3041–0191. OMB’s approval will expire on December 30, 2025. The Commission will consider all comments received in response to this notice before requesting an extension of this collection of information from OMB.

DATES: Submit comments on the collection of information by January 27, 2026.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2017–0044, within 60 days of publication of this notice by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. The Commission typically does not accept comments submitted by email, except as described below.

Mail/hand delivery/courier/written submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail/hand delivery/courier to: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7479.

Instructions: All submissions received must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to cpsc-os@cpsc.gov.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, insert docket number CPSC–2017–0044.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: prra@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

¹ Codified at 12 U.S.C. 5493(b)(3)(A). *See also* Dodd-Frank Act, sec. 1034 (discussing responses to consumer complaints), codified at 12 U.S.C. 5534; sec. 1021(c)(2) (noting that one of the CFPB’s primary functions is “collecting, investigating, and responding to consumer complaints”), codified at 12 U.S.C. 5511(c)(2).

² In addition to the Boarding Form for companies, the Bureau utilizes separate OMB-approved forms to board government agencies and congressional offices onto their own distinct portals to access certain complaint information through OMB Control Number 3170–0057 (Consumer Response Government and Congressional Boarding Forms; expires 12/31/2027).

Title: Safety Standard for Clothing Storage Units.

OMB Number: 3041–0191.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of clothing storage units.

General Description of Collection: Pursuant to 15 U.S.C. 2056f, CPSC promulgated a consumer product safety standard to protect against tip-over of clothing storage units (CSUs). 16 CFR part 1261. That standard incorporates by reference ASTM F2057–23, *Standard Safety Specification for Clothing Storage Units*. Id. 1261.2. A CSU is defined as a “furniture item with drawers and/or hinged doors intended for the storage of clothing typical with bedroom furniture.” Section 3.1.3, ASTM F2057–23. The standard’s requirements include warning labels that contain certain statements and pictograms. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

Identification and labeling requirements provide information to consumers and regulators needed to locate and recall noncomplying products. Identification and labeling requirements include content such as the name and address of the manufacturer. In addition, CSUs must contain warning labels. Warning labels or markings provide information to consumers on hazards and risks associated with product use. The CSU warning label must state: “Children have died from furniture tipover.” Section 10.2.3.1, ASTM F2057–23.

Estimated Number of Respondents: CPSC estimates that approximately 2,122 respondents will design and update the CSU label annually.¹ CPSC estimates that there are approximately 20,103,360 CSU units that will need to be labeled annually.

Estimated Time per Response: The burden associated with the standard includes time spent updating/designing the labeling or marking for a CSU model and time spent attaching the label to a CSU. CPSC estimates that it could take an hour to update/design the labeling or marking for a CSU model. CPSC estimates it could take 0.06 minutes (3.6

seconds or 1,000 labels per hour) to attach the label to the CSU.

Total Estimated Annual Burden: CPSC estimates that it could take an hour to update/design the labeling or marking for a CSU model, therefore, the annual burden is 2,122 hours (based on 2,122 respondents). CPSC estimates that attaching the label to CSUs would amount to an annual burden of 20,103 hours [(0.06 min × 20,103,360 CSUs)/60 mins per hour]. The total estimated annual burden is 22,225 hours.

Total Estimated Annual Cost to Respondents: The total compensation cost per hour worked for private industry workers in goods-producing industries was \$47.00 (March 2025, Table 4, https://www.bls.gov/news.release/archives/ecec_06132025.pdf). Based on this analysis, CPSC estimates that the labor cost of respondent burden is approximately \$1 million annually [(2,122 hours + 20,103 hours) × \$47.00 per hour = \$1,044,575].

In addition to the labor burden costs addressed above, the labeling requirement imposes additional annualized costs. These costs include capital costs for adhesive paper used for each label to be placed on the CSUs. CPSC estimates the cost of the printed label will be about \$0.01. Therefore, the total cost of materials to industry would be about \$200,000 per year (\$0.01 × 20,103,360 units = \$201,033.60).

Request for Comments: The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- whether the collection of information described above is necessary for the proper performance of the Commission’s functions, including whether the information would have practical utility;
- whether the estimated burden of the proposed collection of information is accurate;
- whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2025–21511 Filed 11–26–25; 8:45 am]

BILLING CODE 6355–01–P

U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION

Notice of Public Hearing

AGENCY: U.S. International Development Finance Corporation.

ACTION: Announcement of public hearing.

SUMMARY: The Board of Directors of U.S. International Development Finance Corporation (DFC), in accordance with the Better Utilization of Investments Leading to Development (BUILD) Act of 2018, will hold a public hearing to provide an opportunity for stakeholders to present their views. Those wishing to attend, present at, or submit a written statement to the Board prior to the public hearing must provide advance notice to the agency as detailed below.

DATES: 1:00 p.m. EST, Friday, December 12, 2025.

ADDRESSES: The public hearing will take place virtually. Access information will be provided at the time of attendee registration.

Registration: To attend, present at, or submit a written statement to the Board prior to the public hearing, individuals must notify DFC Corporate Secretary Heather Carroll at corporate.secretary@dfc.gov by 5:00 p.m. EST, Friday, December 5, 2025.

Notices of intent to attend or present at the public hearing must include the individual’s name, title, organization, address, email address, phone number, and a concise summary of the subject matter to be presented. Oral presentations may not exceed five minutes and may be reduced proportionately, if necessary, to afford all participants an opportunity to be heard.

Written statements submitted to the Board prior to the public hearing must include the individual’s name, title, organization, address, email address, and phone number. Statements must be typewritten, double-spaced, and less than ten pages in length.

Lisa Wischkaemper,

Administrative Counsel, Office of the General Counsel.

[FR Doc. 2025–21565 Filed 11–26–25; 8:45 am]

BILLING CODE 3210–02–P

¹ According to 2023 County Business Patterns data published by the U.S. Census Bureau there were between 2,075 and 3,955 establishments manufacturing household furniture: Table CB2300CBP; Upper bound NAICS 33712 (Household and institutional furniture manufacturing), lower bound NAICS 337122 (Nonupholstered wood household furniture manufacturing).

DEPARTMENT OF EDUCATION**[Docket No.: ED–2025–SCC–0943]****Agency Information Collection Activities; Comment Request; Form for Maintenance of Effort Waiver Requests**

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change to a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before January 27, 2026.

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–2025–SCC–0943. 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 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 Todd Stephenson, U.S. Department of Education, Office of Elementary and Secondary Education, 400 Maryland Avenue SW, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Todd Stephenson, (202) 987–1599.

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: Form for Maintenance of Effort Waiver Requests.

OMB Control Number: 1810–0693.

Type of Review: Extension without change to a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 20.

Total Estimated Number of Annual Burden Hours: 1,600.

Abstract: Section 8521(a) of the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA) provides that a local educational agency (LEA) may receive funds under Title I, Part A and other ESEA “covered programs” for any fiscal year only if the State educational agency (SEA) finds that either the combined fiscal effort per student or the aggregate expenditures of the LEA and the State with respect to the provision of free public education by the LEA for the preceding fiscal year was not less than 90 percent of the combined fiscal effort or aggregate expenditures for the second preceding fiscal year. This provision is the maintenance of effort (MOE) requirements for LEAs under the ESEA. If an LEA fails to meet the MOE requirement, under section 8521(b) of the ESEA, the SEA must reduce the amount of funds allocated under the programs covered by the MOE requirement in any fiscal year in the exact proportion by which the LEA fails to maintain effort by falling below 90 percent of either the combined fiscal effort per student or aggregate expenditures, if the LEA has also failed to maintain effort for 1 or more of the 5 immediately preceding fiscal years. In reducing an LEA's allocation because it failed to meet the MOE requirement, the SEA uses the measure most favorable to

the LEA. Section 8521(c) gives the U.S. Department of Education (ED) the authority to waive the ESEA's MOE requirement for an LEA if it would be equitable to grant the waiver due to an exceptional or uncontrollable circumstance such as a natural disaster or a change in the organizational structure of the LEA or a precipitous decline in the LEA's financial resources. If an MOE waiver is granted, the reduction required by section 8521(b) does not occur for that year. A request for a waiver of the MOE requirement is discretionary. Only an LEA that has failed to maintain effort and that believes its failure justifies a waiver would request one. To review an MOE waiver request, ED relies primarily on expenditure, revenue, and other data relevant to an LEA's request provided by the SEA. To assist an SEA with submitting this information, ED developed an MOE waiver form as part of the 2009 Title I, Part A Waiver Guidance, which covered a range of waivers that ED invited at that time. The purpose of this request is to renew approval for the MOE waiver form. This collection includes burden at the SEA level.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2025–21498 Filed 11–26–25; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. CP26–21–000]****National Fuel Gas Supply Corporation; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline**

Take notice that on November 13, 2025, National Fuel Gas Supply Corporation (National Fuel), 6363 Main Street, Williamsville, New York 14221, filed in the above referenced docket, a prior notice request pursuant to sections 157.205, 157.208 and 157.216 of the Commission's regulations under the Natural Gas Act (NGA), and National Fuel's blanket certificate issued in Docket No. CP83–4–000, for authorization to abandon an injection/withdrawal storage well, Well 4985, and a portion of the associated well line VW4985, in its Belmouth Storage Field located in Horton Township, Elk County Pennsylvania (Belmouth Storage Well 4985 Plug and Abandonment Project). National Fuel states that, based on

evaluations, continued use of the well is not deemed feasible, 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 Meghan M. Emes, Senior Counsel, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221, by phone at (716) 857-7004, or by email at emesm@natfuel.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 January 23, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation (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 5:00 p.m. Eastern Time on January 23, 2026. 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 5:00 p.m. Eastern Time on January 23, 2026. 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 5:00 p.m. Eastern Time on January 23, 2026. 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 CP26-21-000 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 CP26-21-000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option

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.

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: Meghan M. Emes, Senior Counsel, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221, or by email (with a link to the document) at emesm@natfuel.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 OPP at (202) 502-6595 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.

Authority: 18 CFR 2.1.

Dated: November 24, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-21493 Filed 11-26-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG26-71-000.

Applicants: Cartwright Solar II LLC.

Description: Cartwright Solar II LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 11/21/25.

Accession Number: 20251121-5191.

Comment Date: 5 p.m. ET 12/12/25.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL26-28-000.

Applicants: County of Yolo, California v. California Independent System Operator Corporation.

Description: Complaint of County of Yolo, California v. California Independent System Operator Corporation.

Filed Date: 11/21/25.

Accession Number: 20251121-5239.

Comment Date: 5 p.m. ET 12/11/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22-1640-007.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2025-11-21 Amendment to Additional Compliance for Order No. 2222 to be effective 9/1/2026.

Filed Date: 11/21/25.

Accession Number: 20251121-5206.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER24-1868-004.

Applicants: El Paso Electric Company.

Description: Compliance filing: El Paso Electric Company submits tariff filing per 35: OATT Revisions—Attachment M to be effective 6/3/2024.

Filed Date: 11/20/25.

Accession Number: 20251120-5260.

Comment Date: 5 p.m. ET 12/11/25.

Docket Numbers: ER25-3146-002.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2025-11-21 SA 4266 Ameren IL 2nd Sub 1st Rev MPFCA J1199 J1453 J1454 (Havana) to be effective 10/11/2025.

Filed Date: 11/21/25.

Accession Number: 20251121-5330.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER25-3284-001.

Applicants: First State Generation, LLC.

Description: Tariff Amendment: First State Generation, LLC submits tariff filing per 35.17(b): Response to Request for Additional Information to be effective 10/25/2025.

Filed Date: 11/20/25.

Accession Number: 20251120-5239.

Comment Date: 5 p.m. ET 12/11/25.

Docket Numbers: ER25-3331-001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Deficiency Response—Clarify Inappropriate Bidding Strategies Regarding EESLs to be effective 8/31/2025.

Accession Number: 20251121-5187.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER25-3508-001.
Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 3927R2 SWEPCO GIA Request for Deferral to be effective 12/31/9998.

Filed Date: 11/21/25.

Accession Number: 20251121-5378.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER25-3511-001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Southwest Power Pool, Inc. submits tariff filing per 35.17(b): 3878R1 States Edge Wind I GIA Request for Deferral to be effective 12/31/9998.

Filed Date: 11/21/25.

Accession Number: 20251121-5362.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER25-3512-001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 3879R1 States Edge Wind I GIA Request for Deferral to be effective 12/31/9998.

Filed Date: 11/21/25.

Accession Number: 20251121-5380.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER25-3513-001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Southwest Power Pool, Inc. submits tariff filing per 35.17(b): 3880R1 States Edge Wind I GIA Request for Deferral to be effective 12/31/9998.

Filed Date: 11/21/25.

Accession Number: 20251121-5402.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26-16-001.

Applicants: Petersburg Energy Center, LLC.

Description: Tariff Amendment: Amendment of Certificate of Concurrence to be effective 10/3/2025.

Filed Date: 11/21/25.

Accession Number: 20251121-5405.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26-71-001.

Applicants: NorthWestern Energy Public Service Corporation, Southwest Power Pool, Inc.

Description: Tariff Amendment: NorthWestern Energy Public Service Corporation submits tariff filing per 35.17(b): NorthWestern Energy's Amended Formula Rate Revisions to Comply with Order 898 to be effective 12/8/2025.

Filed Date: 11/21/25.

Accession Number: 20251121-5248.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26-562-000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: Revisions to Attachment AF Regarding

the Local Market Power Test to be effective 1/21/2026.

Filed Date: 11/20/25.

Accession Number: 20251120–5241.

Comment Date: 5 p.m. ET 12/11/25.

Docket Numbers: ER26–564–000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2025–11–21 Rate Schedule 59 MISO–AECI Joint Planning Agreement to be effective 1/21/2026.

Filed Date: 11/21/25.

Accession Number: 20251121–5055.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–566–000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: 205(d) Rate Filing: 2025–11–21 SA 3770 NIPSCO–Carpenter Wind Farm 1st Rev GIA (J1069) to be effective 11/13/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5073.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–567–000.

Applicants: Avista Corporation.

Description: 205(d) Rate Filing: Avista Corp OATT Revisions to Ancillary Service Schedules to be effective 1/1/2026.

Filed Date: 11/21/25.

Accession Number: 20251121–5123.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–568–000.

Applicants: PacifiCorp.

Description: 205(d) Rate Filing: Revisions to General Transfer Agreement, PacifiCorp Rate Schedule No. 237 to be effective 1/1/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5145.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–569–000.

Applicants: Southwestern Public Service Company, Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: Southwestern Public Service Company submits tariff filing per 35.13(a)(2)(iii): 4535 Invenergy Storage Development & SPS Facilities Service Agr to be effective 1/21/2026.

Filed Date: 11/21/25.

Accession Number: 20251121–5173.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–570–000.

Applicants: New York Independent System Operator, Inc.

Description: 205(d) Rate Filing: NYISO 205: Proposed Revisions to Implement CHPE MTF to be effective 1/21/2026.

Filed Date: 11/21/25.

Accession Number: 20251121–5190.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–571–000.

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): Amber Meadow Solar Amendment of LGIA to be effective 11/17/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5221.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–572–000.

Applicants: Southern California Edison Company.

Description: 205(d) Rate Filing: Southern California Edison Company submits tariff filing per 35.13(a)(2)(iii): Letter Agreement, Simon Project, TOT1030, SA # 370 to be effective 11/22/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5229.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–573–000.

Applicants: Black Hills Power, Inc.

Description: 205(d) Rate Filing: Black Hills Power, Inc. submits tariff filing per 35.13(a)(2)(iii): Ministerial Clean Up Tariff Filing to be effective 8/1/2024.

Filed Date: 11/21/25.

Accession Number: 20251121–5231.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–574–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Notice of Cancellation of WMPA Service Agreement No. 7031; Queue No. AF2–416 to be effective 1/21/2026.

Filed Date: 11/21/25.

Accession Number: 20251121–5272.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–575–000.

Applicants: Westlands Grape, LLC.

Description: 205(d) Rate Filing: Westlands Grape Certificate of Concurrence to SFA to be effective 12/1/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5320.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–576–000.

Applicants: Energy Prepay XI, LLC.

Description: Initial Rate Filing: Baseline new to be effective 11/22/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5328.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–577–000.

Applicants: FPL Energy Wyman IV LLC.

Description: 205(d) Rate Filing: FPL Energy Wyman IV LLC submits tariff filing per 35.12: ISO–NE Schedule 17–IROL–CIP Cost Recovery Rate Schedule to be effective 11/22/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5349.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–578–000.

Applicants: ISO New England Inc., New England Power Pool.

Description: ISO New England Inc., et al.; Filing of Installed Capacity Requirements, Hydro-Quebec Interconnection Capability Credits and Related Values for 2026–2027 and 2027–2028.

Filed Date: 11/21/25.

Accession Number: 20251121–5371.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER26–579–000.

Applicants: LPH Marketing, LLC.

Description: 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 11/22/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5385.

Comment Date: 5 p.m. ET 12/12/25.

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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: November 21, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–21331 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Project No. 2100–134]****California Department of Water Resources; Notice of Meeting**

a. *Project Name and Number:* Feather River Hydroelectric Project No. 2100–134.

b. *Applicant:* California Department of Water Resources.

c. *Date and Time of Meeting:* Tuesday, December 16th, 2025, from 2:00 p.m. to 3:00 p.m. Eastern Standard Time (11:00 a.m. to 12:00 p.m. Pacific Standard Time).

d. *FERC Contact:* Ousmane Sidibe at (202) 502–6245 or ousamane.sidibe@ferc.gov.

e. *Purpose of Meeting:* As requested by the Mooretown Rancheria of Maidu Indians, Commission staff will hold a meeting with representatives from the Tribe to discuss the Tribe's concerns for the proposed relicensing of the Feather River Hydroelectric Project. The meeting will be held virtually via Microsoft Teams.

f. Intervenor in the referenced proceeding may attend the meeting as observers; however, participation will be limited to representatives from the Mooretown Rancheria of Maidu Indians and Commission staff. If meeting attendees decide to disclose information about a specific location which could create a risk or harm to an archaeological site or Native American cultural resource, attendees other than representatives from the Mooretown Rancheria of Maidu Indians and Commission staff will be excused for that portion of the meeting.

g. A summary of the meeting will be placed in the public record of this proceeding. As appropriate, the meeting summary will include both a public, redacted version that excludes any information about the specific location of the archeological site or Native American cultural resource and an unredacted privileged version. Intervenor planning to attend the meeting should notify Ousmane Sidibe at (202) 502–6245 or ousamane.sidibe@ferc.gov by Friday, December 12th to RSVP and to receive specific instructions for logging in to the meeting.

Authority: 18 CFR 2.1.

Dated: November 24, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21492 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. CP26–19–000]****Columbia Gas Transmission, LLC; Notice of Application and Establishing Intervention Deadline**

Take notice that on November 10, 2025, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed an application under Sections 7(b) and 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations requesting authorization for its NKY Gate Enhancement Project (Project). The Project consists of replacement of vintage pipeline infrastructure originally installed in the 1950s with new, modern pipeline facilities to reduce potential safety and reliability risks and ensure continued compliance with evolving federal and state regulations, including those administered by the Pipeline and Hazardous Materials Safety Administration (PHMSA). Specifically, the Project involves the abandonment of approximately 50 miles of pipeline as well as the construction of about 31 miles of pipeline and various aboveground facilities in Kentucky and Ohio. The total estimated cost of the Project is \$429 million; all as more fully set forth in the application which is on file with the Commission and open for 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.reference.room@ferc.gov.

Any questions concerning this application should be directed to David A. Alonzo, Manager, Project Authorizations, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, at (832) 320–5477 or by email david_alonzo@tcenergy.com.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,¹ within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Water Quality Certification

Columbia stated that a water quality certificate under section 401 of the Clean Water Act is required for the project from the Kentucky Energy and Environment Cabinet—Department of Environmental Protection. When available, Columbia should submit to the Commission a copy of the request for certification for the Commission authorization, including the date the request was submitted to the certifying agency, and either (1) a copy of the certifying agency's decision or (2) evidence of waiver of water quality certification.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 15, 2025. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as

¹ 18 CFR 157.9.

interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or *OPP@ferc.gov*.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)² and 385.211³ of the Commission's regulations under the NGA, any person⁴ may file a protest to the application. Protests must comply with the requirements specified in section 385.2001⁵ of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on December 15, 2025.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP26-19-000 in your submission.

(1) 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;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Comment on a Filing"; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP26-19-000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502-8258 or *FercOnlineSupport@ferc.gov*.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, 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. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,⁶ 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 Procedure⁷ and the regulations under the NGA⁸ by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on December 15, 2025. 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>.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP26-19-000 in your submission.

(1) You may file your motion to intervene 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 "Intervention." The eFiling feature includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP26-19-000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (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: David A. Alonzo, Manager, Project Authorizations, Columbia Gas Transmission,

LLC, 700 Louisiana Street, Suite 1300, Houston, Texas, 77002-2700 or by email (with a link to the document) *david_alonzo@tcenergy.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. Service can be via email with a link to the document.

All timely, unopposed⁹ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹⁰ Motions to intervene that are filed after the intervention deadline are untimely, and

² 18 CFR 157.10(a)(4).

³ 18 CFR 385.211.

⁴ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁵ 18 CFR 385.2001.

⁶ 18 CFR 385.102(d).

⁷ 18 CFR 385.214.

⁸ 18 CFR 157.10.

⁹ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹⁰ 18 CFR 385.214(c)(1).

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.¹¹ 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.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502-6595 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.

Intervention Deadline: 5:00 p.m. Eastern Time on December 15, 2025.
(Authority: 18 CFR 2.1).

Dated: November 24, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-21490 Filed 11-26-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7591-001]

James D. Sysko; Notice of Proposed Termination of Exemption by Implied Surrender and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric proceeding has been initiated by the Commission and is available for public inspection:

a. *Type of Proceeding:* Proposed Termination of Exemption by Implied Surrender.

b. *Project No:* 7591-001.

c. *Date Initiated:* October 21, 2025.

d. *Applicant:* James D. Sysko.

e. *Name of Project:* Wight Brook Hydroelectric Project.

f. *Location:* The project is located in the town of Newry, Oxford County, Maine. The project does not occupy federal lands.

g. *Filed Pursuant to:* 18 CFR 4.106.

h. *Applicant Contact:* James D. Sysko, 524 Jims Drive, Newry, Maine 04261, (207) 824-3244.

i. *FERC Contact:* Maryam Akhavan, (202) 502-6110, maryam.akhavan@ferc.gov.

j. *Resource Agency Comments:* Federal, state, local and Tribal agencies are invited to file comments on the described proceeding. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments.

k. *Deadline for filing comments, motions to intervene, and protests:* December 5, 2025 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P-7591-001. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor 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.

l. *Description of Project Facilities:* The project works originally included: a 1.7-foot-high, 30-foot-long concrete diversion dam, an inlet structure, a 1,700-foot-long, 10-inch-diameter penstock, a powerhouse containing a single 30-kW turbine generator, a 1,400-foot-long, 7.2-kV underground transmission line, and appurtenant facilities. The dam is located upstream of a recreation area on Wight Brook and the powerhouse is located on a private property not owned by the exemptee.

m. *Description of Proceeding:* The exemptee is in violation of Standard Article 1 of its exemption, which was granted on December 23, 1983 (25 FERC § 62,401). The Commission's regulation 18 CFR 4.106 provides, among other things, that the Commission reserves the right to revoke an exemption if any term or condition of the exemption is violated. The project has not operated since 2019.

Between 2014 and 2019, the property owner of the land where the powerhouse is located dissolved the easement that allowed the exemptee access to the project works. The project has been partially decommissioned, a notch has been cut out of the dam, the penstock partially removed, the powerhouse has been demolished and disconnected from the grid. On May 8, 2024 and September 26, 2024, Commission staff issued letters requesting updated contact information for the new owner of the easement and an application for the project's surrender as the project had been rendered permanently inoperable. The exemptee did not respond to the Commission's correspondence.

n. *Location of the Order Issuing Exemption:* The order 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. 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, call 1-866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659.

o. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

p. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and

¹¹ 18 CFR 385.214(b)(3) and (d).

Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

q. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

r. 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, community organizations, 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: October 21, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025-21335 Filed 11-26-25; 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 accounting Request filings:

Docket Numbers: AC26-10-000.

Applicants: American Electric Power Service Corporation.

Description: The Public Service Company of Oklahoma submits request for approval of proposed journal entries re acquisition of Pixley Solar Energy LLC, Flat Ridge 4 Wind, LLC, and Flat Ridge 5 Wind Energy LLC.

Filed Date: 11/21/25.

Accession Number: 20251121-5590.

Comment Date: 5 p.m. ET 12/12/25.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG26-72-000.

Applicants: Westlands Grape, LLC.

Description: Westlands Grape, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 11/24/25.

Accession Number: 20251124-5169.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: EG26-73-000.

Applicants: Westlands VI Project, LLC.

Description: Westlands VI Project, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 11/24/25.

Accession Number: 20251124-5171.

Comment Date: 5 p.m. ET 12/15/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18-1156-005.

Applicants: St. Joseph Energy Center, LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 11/21/25.

Accession Number: 20251121-5512.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER21-1635-013.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Compliance Filing of Tariff Records to Implement Settlement in ER21-1635-009 to be effective 1/1/2024.

Filed Date: 11/24/25.

Accession Number: 20251124-5354.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER22-2305-000.

Applicants: Louisville Gas and Electric Company.

Description: Report Filing: Order 881 Motion for Additional Deferral to be effective N/A.

Filed Date: 11/21/25.

Accession Number: 20251121-5370.

Comment Date: 5 p.m. ET 12/8/25.

Docket Numbers: ER25-3070-002.

Applicants: Midcontinent Independent System Operator, Inc., Indianapolis Power & Light Company.

Description: Tariff Amendment: Indianapolis Power & Light Company submits tariff filing per 35.17(b): 2025-11-21_2nd Amendment IPL dba AES

Transition to Forward Looking Formula Rate to be effective 1/1/2026.

Filed Date: 11/21/25.

Accession Number: 20251121-5434.

Comment Date: 5 p.m. ET 12/12/25.

Docket Numbers: ER25-3162-002.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 1768R2 American Electric Power NITSA and NOAs—Amended to be effective 6/1/2025.

Filed Date: 11/24/25.

Accession Number: 20251124-5198.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER25-3334-001.

Applicants: City of Anaheim, California.

Description: Tariff Amendment: City of Anaheim, Cal. Response to Deficiency Letter to be effective 9/1/2025.

Filed Date: 11/24/25.

Accession Number: 20251124-5343.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER25-3349-001.

Applicants: City of Riverside, California.

Description: Tariff Amendment: City of Riverside, Cal. Response to Deficiency Letter to be effective 9/1/2025.

Filed Date: 11/24/25.

Accession Number: 20251124-5356.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER26-403-001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Proposed Tariff Amendments—Request to Change Requested Effective Date to be effective 1/30/2026.

Filed Date: 11/24/25.

Accession Number: 20251124-5250.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER26-584-000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: 205(d) Rate Filing: 2025-11-24_SA 1039 1040 1041 1042 MPPA 3rd Rev TSAs to be effective 1/24/2026.

Filed Date: 11/24/25.

Accession Number: 20251124-5200.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER26-585-000.

Applicants: Idaho Power Company.

Description: 205(d) Rate Filing: Modification to Attachment O, Section 8 to be effective 1/26/2026.

Filed Date: 11/24/25.

Accession Number: 20251124-5204.

Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER26-586-000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 3490R2 AEP Energy Partners, Inc. NITSA and NOA to be effective 11/1/2025.

Filed Date: 11/24/25.
Accession Number: 20251124–5208.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–587–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 205(d) Rate Filing: 2025–11–24 SA 3454 Entergy Arkansas-Flat Fork Solar 4th Rev GIA (J907 J1434) to be effective 11/19/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5223.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–588–000.
Applicants: PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Amendment to NSA, SA No. 6264; Queue Nos. V1–026/V1–027 to be effective 1/24/2026.
Filed Date: 11/24/25.
Accession Number: 20251124–5229.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–589–000.
Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.
Description: 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): NMPG 205: Revisions to FRT and associated protocols.
Filed Date: 11/24/25.
Accession Number: 20251124–5277.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–590–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 205(d) Rate Filing: 2025–11–24 SA 4596 Entergy Louisiana-Entergy Louisiana GIA (E0014) to be effective 11/19/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5333.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–591–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Notice of Cancellation of ISA, SA No. 7033; AF2–166 re: Withdrawn to be effective 1/24/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5361.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–592–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: Initial rate filing: Alabama Power Company submits tariff filing per 35.12: PowerSouth Affected System Upgrade Agreement Filing to be effective 11/17/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5369.
Comment Date: 5 p.m. ET 12/15/25.

Docket Numbers: ER26–593–000.
Applicants: Georgia Power Company.
Description: Initial rate filing: PowerSouth (Lowman #3) Affected System Upgrade Agreement Concurrence Filing to be effective 11/17/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5371.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–594–000.
Applicants: Mississippi Power Company.
Description: Initial rate filing: PowerSouth (Lowman #3) Affected System Upgrade Agreement Concurrence Filing to be effective 11/17/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5373.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–595–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Notice of Cancellation of SA No. 6705; AE1–056 re: Withdrawn to be effective 1/24/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5386.
Comment Date: 5 p.m. ET 12/15/25.
Docket Numbers: ER26–596–000.
Applicants: PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Original NSA, Service Agreement No. 7774; AF1–119/AF2–162 to be effective 10/28/2025.
Filed Date: 11/24/25.
Accession Number: 20251124–5410.
Comment Date: 5 p.m. ET 12/15/25.
 Take notice that the Commission received the following qualifying facility filings:
Docket Numbers: QF26–212–000.
Applicants: MDC002.B2 PROJECTCO, LLC.
Description: Form 556 of MDC002.B2 PROJECTCO, LLC.
Filed Date: 11/21/25.
Accession Number: 20251121–5586.
Comment Date: 5 p.m. ET 12/12/25.
 The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: November 24, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–21414 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26–22–000]

Saltville Gas Storage Company L.L.C.; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on November 13, 2025, Saltville Gas Storage Company L.L.C. (Saltville), 915 N Eldridge Parkway, Suite 1100, Houston, Texas 77079, filed in the above referenced docket, a prior notice request pursuant to sections 157.205, 157.213 and 157.216 of the Commission's regulations under the Natural Gas Act (NGA), and Saltville's blanket certificate issued in Docket No. CP04–15–000, for authorization to abandon one injection/withdrawal (I/W) well and associated facilities at its Early Grove natural gas storage facility in Scott County, Virginia. Specifically, Saltville proposes to (i) permanently plug and abandon I/W well EH 90 and (ii) abandon and remove associated facility piping approximately 1,100 feet of 2-inch-diameter piping, wellhead, and appurtenant equipment (Project). The estimated cost for the Project is \$2,000,000; 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 Anish George, Manager, Regulatory, Saltville Gas Storage Company L.L.C., 915 N Eldridge Parkway, Suite 1100, Houston, Texas 77079, by phone at (713) 627-5120, or by email at anish.george@enbridge.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 January 20, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or request for rehearing, contact the Office of Public Participation 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 5:00 p.m. Eastern Time on January 20, 2026. 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 5:00 p.m. Eastern Time on January 20, 2026. 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 5:00 p.m. Eastern Time on January 20, 2026. 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 CP26-22-000 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";⁶ or

(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 CP26-22-000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, 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: Anish George, Manager, Regulatory, Saltville Gas Storage Company L.L.C., 915 N Eldridge Parkway, Suite 1100, Houston, Texas 77079, or by email (with a link to the document) at anish.george@enbridge.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact

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.

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.

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 OPP at (202) 502-6595 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/subscription.asp.

Dated: November 21, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-21329 Filed 11-26-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26-2-000]

Enable Mississippi River Transmission, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Big Hollow Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Big Hollow Project involving construction and operation of facilities by Enable Mississippi River Transmission, LLC (EMRT) in Monroe County, Illinois and Jefferson County, Missouri. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes

into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as "scoping." The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on November 28, 2025. Comments may be submitted in written form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on October 6, 2025, you will need to file those comments in Docket No. CP26-2-000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement

agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

EMRT provided landowners with a fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas, Landowner Topics link.

Public Participation

There are three methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208-3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; a comment on a particular project is considered a "Comment on a Filing"; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP26-2-000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, 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,

Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. 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, community organizations, 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.

Summary of the Proposed Project

EMRT proposes to construct and operate an approximate 9.6-mile-long, 20-inch diameter lateral pipeline, measurement and regulation station, and appurtenant facilities in Monroe County, Illinois and Jefferson County, Missouri. The Big Hollow Project would provide about 200,000 million standard cubic feet of natural gas per day to the existing Big Hollow Energy Center site. According to EMRT, its project would facilitate Ameren's new gas-fired generation at the Big Hollow Energy Center on the site of their retired Rush Island Energy Center.

The Big Hollow Project would consist of the following facilities:

- an approximate 9.6-mile-long, 20-inch diameter lateral pipeline, from a point of interconnection on EMRT's existing 22-inch-diameter Mainline 2 (ML2) and 26-inch-diameter Mainline pipelines, and appurtenances at Mile Post 415.5 in Monroe County, Illinois to the existing Big Hollow Energy Center site in Jefferson County, Missouri;
- a Measurement and Regulation Station; and
- appurtenant pipeline facilities including: 20-inch pig launcher and 20-inch pig receiver, 20-inch hot tap on existing ML2 and Mainline 3 locations.

The general location of the project facilities is shown in appendix 2.¹

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the

Land Requirements for Construction

Construction of the proposed facilities would disturb about 129 acres of land for the above-ground facilities and the pipeline. Following construction, EMRT would maintain about 78 acres for permanent operation of the project's facilities; the remaining acreage would be restored and allowed to revert to former uses.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed project under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received

appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary." For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll free, (886) 208-3676 or TTY (202) 502-8659.

during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary² and the Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environmental/environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.³ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.⁴

The environmental document for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose

² For instructions on connecting to eLibrary, refer to the last page of this notice.

³ Cooperating agency responsibilities are addressed in Section 107(a)(3) of NEPA (42 U.S.C. 4336(a)(3)).

⁴ The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number CP26–2–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached “Mailing List Update Form” (appendix 1).

Additional Information

Additional information about the project is 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. Click on the eLibrary link, click on “General Search” and enter the docket number in the “Docket Number” field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission’s calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

Dated: October 21, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21334 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD24–7–000]

Federal and State Current Issues Collaborative; Notice Postponing Meeting

On March 21, 2024, the Federal Energy Regulatory Commission (Commission), pursuant to 16 U.S.C. 824h(b), established a Federal and State Current Issues Collaborative (Collaborative) to provide a venue for Federal and State regulators to share perspectives, increase understanding, and, where appropriate, identify potential solutions regarding challenges and coordination on matters that implicate both State and Federal regulatory jurisdiction.¹

The public meeting of the Collaborative set for November 12, 2025, in Seattle, Washington,² is postponed to February 2026 during the National Association of Regulatory Utility Commissioners’ Winter Policy Summit in Washington, DC.

In light of the lapse in Federal appropriations, the Commission limited travel. The Commission is open and operational.

More information about the Collaborative is available here: <https://www.ferc.gov/federal-state-current-issues-collaborative>. For questions related to the Collaborative, please contact: Robert Thormeyer, 202–502–8694, robert.thormeyer@ferc.gov; Joseph Popely, 202–502–8513, joseph.popely@ferc.gov; or Kimberly Duffley, 202–898–1305, kduffley@naruc.org.

Dated: November 5, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21357 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

¹ *Fed. and State Current Issues Collaborative*, 186 FERC ¶ 61,189 (2024).

² *Fed. and State Current Issues Collaborative*, Notice Announcing Meeting, Docket No. AD24–7–000 (issued Oct. 6, 2025).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF25–10–000]

Corpus Christi Liquefaction Stage IV, LLC, Corpus Christi Liquefaction, LLC, Cheniere Corpus Christi Pipeline, L.P.; Notice of Scoping Period Requesting Comments on Environmental Issues for the Planned CCL Stage 4 Project and CCPL Expansion Project, and Notice of Public Scoping Session

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the planned CCL Stage 4 Project and CCPL Expansion Project (projects) involving construction and operation of facilities by Corpus Christi Liquefaction Stage IV, LLC, Corpus Christi Liquefaction, LLC, and Cheniere Corpus Christi Pipeline, L.P. (collectively, the Applicants) in San Patricio and Nueces Counties, Texas. The Commission will use this environmental document in its decision-making process to determine whether the projects are in the public interest.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the projects. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of an authorization. This gathering of public input is referred to as “scoping.” The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission’s NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on December 24, 2025. Comments may be submitted in written or oral form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written or oral comments during the preparation of the environmental document.

If you submitted comments on these projects to the Commission before the opening of this docket on July 17, 2025, you will need to file those comments in Docket No. PF25–10–000 to ensure they are considered.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of these planned projects and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the projects, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement

agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas, Landowner Topics *link*.

Public Participation

There are four methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (www.ferc.gov)

under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; a comment on a particular project is considered a "Comment on a Filing"; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (PF25–10–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

(4) In lieu of sending written comments, the Commission invites you to attend a public scoping session its staff will conduct in the project area, scheduled as follows:

Date and time	Location
Wednesday, December 10, 2025, 5:00–8:00 p.m. CST	Portland Community Center, 2000 Billy G. Webb Drive, Portland, TX 78374, 361–777–4670.

The primary goal of the scoping session is to have you identify the specific environmental issues and concerns that should be considered in the environmental document. Individual oral comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of oral comments in a convenient way during the timeframe allotted.

The scoping session is scheduled from 5:00 p.m. to 8:00 p.m. CST. You may arrive at any time after 5:00 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival. Comments will be taken until 8:00 p.m. However, if no additional numbers have been handed out and all individuals

who wish to provide comments have had an opportunity to do so, staff may conclude the session at 7:30 p.m. Please see appendix 1 for additional information on the session format and conduct.¹

Your scoping comments will be recorded by a court reporter (with FERC staff or representative present) and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system (see the last page of this notice for instructions on using eLibrary). If a

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary." For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at FercOnlineSupport@ferc.gov or call toll free, (866) 208–3676 or TTY (202) 502–8659.

significant number of people are interested in providing oral comments in the one-on-one settings, a time limit of 5 minutes may be implemented for each commentor.

It is important to note that the Commission provides equal consideration to all comments received, whether filed in written form or provided orally at a scoping session. Although there will not be a formal presentation, Commission staff will be available throughout the scoping session to answer your questions about the environmental review process. Representatives from Cheniere will also be present to answer project-specific questions.

Additionally, the Commission offers a free service called eSubscription, which makes it easy to stay informed of all issuances and submittals regarding the

dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202)502-6595 or *OPP@ferc.gov*.

Summary of the Planned Project

Corpus Christi Liquefaction Stage IV, LLC and Corpus Christi Liquefaction, LLC plan to construct and operate an expansion of the existing Corpus Christi Liquefaction Terminal (CCL Terminal) in San Patricio and Nueces Counties, Texas on the La Quinta Ship Channel. The proposed CCL Terminal expansion consists of four new liquefaction trains, two liquefied natural gas (LNG) storage tanks, three ground flares, a third marine berth, and other associated infrastructure (collectively, the "CCL Stage 4 Project"). CCL Stage 4 Project anticipates an additional 390 LNG vessels per year, increasing the approximate number at the CCL Terminal from the currently authorized 480 LNG vessels per year to 870 per year.

Cheniere Corpus Christi Pipeline, L.P. plans to construct and operate a 26-mile-long, 42-inch-diameter interstate natural gas pipeline loop² (partially collocated with its existing 48-inch-diameter pipeline), as well as additional compression and interconnect facilities, all within San Patricio County, Texas (collectively the "CCPL Expansion Project"). The CCPL Expansion Project would provide feed gas on an integrated basis to the CCL Terminal and include receipt meters to allow it to interconnect with pipelines to be developed by others in the future. The CCPL Expansion Project would increase gas delivery capacity to the CCL Terminal by approximately 3.0 billion standard cubic feet per day.

The CCL Stage 4 Project would consist of the following facilities:

- four large-scale liquefaction trains (Trains 4-7);
- four inlet air chilling units;
- two full containment, aboveground 220,000-cubic-meter LNG storage tanks;
- a new marine berth;
- one marine loading jetty;
- seven boil-off-gas compressors (BOG);

- one new main substation;
- one marine totally enclosed ground flare;

• three multi-point ground flares;

• a new 48-inch-diameter, approximately 1-mile-long pipeline from the Stage 4 Custody Meter Station to the CCL Terminal custody meter station where the existing 48-inch diameter pipeline intersects the terminal;

- new flare knockout drums and other new utilities and appurtenant facilities; and
- tie-ins to the existing CCL Terminal, including shared utilities, LNG rundown header, elevated flares, BOG, LNG loading lines, and the project's feed gas header.

The CCPL Expansion Project would consist of the following facilities:

- a new compressor station (Sinton 2 Compressor Station) adjacent to the existing Sinton Compressor Station (previously authorized in Docket No. CP12-508-000) with a proposed 105,000 horsepower;
- a new 42-inch-diameter, approximately 26-mile-long pipeline loop from the Sinton and Sinton 2 Compressor Stations to the Stage 4 Custody Meter Station; and
- interconnect, metering, and flow control infrastructure between the existing and planned facilities.

According to the Applicants, the purpose of the planned projects is to liquefy and export additional LNG volumes from the CCL Terminal to meet increased international demand for natural gas. The general location of the project facilities is shown in appendix 2.

Land Requirements for Construction

Construction of the CCL Stage 4 Project would disturb up to 2,203 acres of land, of which 1,465.2 acres include the existing CCL Stage 4 Terminal and Marine Facilities, and 414.7 acres include land outside the previously approved CCL Terminal site. Following construction, 365.0 acres of land would be added to the current CCL Terminal footprint; the remaining acreage would be restored and reverted to former uses.

Construction of the CCPL Expansion Project would disturb about 581.4 acres of land, which includes 520.5 acres for pipeline construction, 26.7 acres for aboveground facility construction, and 34.2 acres for temporary pipeline contractor yards. Following construction, Cheniere Corpus Christi Pipeline, L.P. would maintain and operate 165.4 acres of pipeline right-of-way and 26.7 acres of aboveground facility. About 95 percent of the planned

pipeline route parallels existing pipeline, utility, or road rights-of-way.

In total, construction of the projects would disturb 2,784.4 acres of land and 2,022.3 acres of land would be operated as the CCL Terminal, pipeline right-of-way, and pipeline aboveground facilities.

NEPA Process and the Environmental Document

Any environmental document issued by Commission staff will discuss impacts that could occur as a result of the construction and operation of the planned projects under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- socioeconomics;
- land use;
- air quality and noise; and
- reliability and safety.

Commission staff have already identified several issues that deserve attention based on a preliminary review of the planned facilities and the environmental information provided by the Applicants. This preliminary list of issues may change based on your comments and our analysis:

- visual effects from increased flare activity;
- increased emissions from operation of the CCL Terminal;
- increased ship transit and potential shoreline effects from wake waves; and
- marine berth construction and ship transit effects on marine species.

Commission staff will also evaluate reasonable alternatives to the planned projects or portions of the projects and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Although no formal application has been filed, Commission staff have already initiated a NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the Commission receives an application. As part of the pre-filing review, Commission staff will contact federal and state agencies to discuss their involvement in the scoping process and the preparation of the environmental document.

² A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

If a formal application is filed, Commission staff will then determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the environmental issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its determination on the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued once an application is filed, which will open an additional public comment period. Staff will then prepare a draft EIS that will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS, and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary³ and the Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to these projects to formally cooperate in the preparation of the environmental document.⁴ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice. Currently, the U.S. Army Corps of Engineers has expressed its intention to participate as a cooperating agency in the preparation of the environmental document to satisfy its NEPA responsibilities related to these projects.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.⁵ The environmental document for these projects will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the projects and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the planned projects.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number (PF25–10–000) in your request. If you are requesting a change to your address, please be sure

to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached "Mailing List Update Form" (appendix 3).

Becoming an Intervenor

Once the Applicants file its application with the Commission, you may want to become an "intervenor" which is an official party to the Commission's proceeding. Only intervenors have the right to seek rehearing of the Commission's decision and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Motions to intervene are more fully described at <https://www.ferc.gov/how-intervene>. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the projects, after which the Commission will issue a public notice that establishes an intervention deadline.

Additional Information

Additional information about these projects are available on the FERC website (www.ferc.gov) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number in the "Docket Number" field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

Authority: 18 CFR 2.1.

Dated: November 24, 2025

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21489 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

³ For instructions on connecting to eLibrary, refer to the last page of this notice.

⁴ Cooperating agency responsibilities are addressed in Section 107(a)(3) of NEPA (42 U.S. Code § 4336(a)(3)).

⁵ The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

[P-2735-105]

**Pacific Gas and Electric Company;
Notice of Application Accepted for
Filing and Soliciting Comments,
Motions to Intervene, and Protests**

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Amendment of license to replace and refurbish pump/generator units.

b. *Project No.:* 2735-105.

c. *Date Filed:* May 30, 2025.

d. *Applicant:* Pacific Gas and Electric Company.

e. *Name of Project:* Helms Pumped Storage Project.

f. *Location:* The project is located on the North Fork Kings River and Helms Creek in Fresno County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)-825(r).

h. *Applicant Contact:* Mr. Dave Gabbard, Pacific Gas and Electric Company, Vice President, Power Generation, 300 Lakeside Drive, Oakland, CA 94612.

i. *FERC Contact:* Mr. Steven Sachs, (202) 502-8666, Steven.Sachs@ferc.gov.

j. *Cooperating agencies:* With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item l. below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. *Water Quality Certification:* The applicant must file no later than 60 days following the date of issuance of this notice: (1) a 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 waiver of water quality certification.

l. *Deadline for filing comments, motions to intervene, and protests:* December 22, 2025, 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments,

motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P-2735-105. Comments emailed to Commission staff are not part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor 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.

m. *Description of Request:* The applicant requests to amend its license to replace all three pump/turbines and refurbish each motor/generator. The changes would result in an increase in the hydraulic capacities from 7,530 to 8,640 cubic feet per second (cfs) while pumping and 10,500 to 12,050 cfs while generating. The proposal would also result in an increase in electrical consumption from 1,035 to 1,170 megawatts (MW) while pumping and increase production from 1,212 to 1,392 MW while generating. Construction activities would occupy a total of approximately 8.2 acres of land and may require temporary interruptions of access to recreation facilities along Powerhouse Road including the Wishon boat ramp, the Helms Picnic Area, and the Short Hair Creek fishing access. Construction is expected to take 3 years and would commence in 2029.

n. *Locations of the application:* 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. 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, call 1-866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659.

o. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

p. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

q. *Filing and Service of Documents:* Any filing must: (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

r. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

Dated: November 21, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025-21327 Filed 11-26-25; 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: PR26–17–000.

Applicants: Louisville Gas and Electric Company.

Description: 284.123(g) Rate Filing: LGE Revised Statement of Operating Conditions to be effective 11/1/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5398.

Comment Date: 5 p.m. ET 12/12/25.

284.123(g) Protest: 5 p.m. ET 1/20/26.

Docket Numbers: RP26–227–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: 4(d) Rate Filing: Rate Schedule S–2 Tracker Filing Eff 12/1/2025 to be effective 12/1/2025.

Filed Date: 11/21/25.

Accession Number: 20251121–5292.

Comment Date: 5 p.m. ET 12/3/25.

Docket Numbers: RP26–228–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: 4(d) Rate Filing: SNG SCRM Filing 2025 to be effective 1/1/2026.

Filed Date: 11/24/25.

Accession Number: 20251124–5214.

Comment Date: 5 p.m. ET 12/8/25.

Docket Numbers: RP26–229–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: Compliance filing: SNG Operational Transactions Filing 2025 to be effective N/A.

Filed Date: 11/24/25.

Accession Number: 20251124–5260.

Comment Date: 5 p.m. ET 12/8/25.

Docket Numbers: RP26–230–000.

Applicants: Natural Gas Pipeline Company of America LLC.

Description: 4(d) Rate Filing: Negotiated Rate Agreements—Municipal Customers December 2025 to be effective 12/1/2025.

Filed Date: 11/24/25.

Accession Number: 20251124–5263.

Comment Date: 5 p.m. ET 12/8/25.

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/fercensearch.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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or (202) 502–6595 or OPP@ferc.gov.

Dated: November 24, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–21415 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. CP26–28–000]

Rockies Express Pipeline, LLC; Notice Of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on November 18, 2025, Rockies Express Pipeline, LLC (REX), 370 Van Gordon Street, Lakewood, Colorado 80228–1519, filed in the above referenced docket, a prior notice request pursuant to sections 157.205, 157.208, 157.210, and 157.211 of the Commission's regulations under the Natural Gas Act (NGA), and REX's blanket certificate issued in Docket No. CP04–415–000, for authorization to construct, own, operate, and maintain: (1) a new interconnect (Switchgrass Interconnect Site) at REX's existing Cheyenne Hub in Weld County, Colorado, (2) approximately 7.2 miles of new 36-inch-diameter natural gas pipeline (Switchgrass Lateral), extending from Section 5, Township 11N, Range 66W in Weld County, Colorado, to Section 7, Township 12N, Range 66W, Laramie County, Wyoming, and (3) a new meter station (Switchgrass Meter Station), located in Laramie County, Wyoming (Switchgrass Interconnect Project). The project will allow REX to provide 419,000 dekatherms per day (Dth/d) of incremental firm transportation service

on its system from the new Switchgrass Interconnect Site to the new Switchgrass Meter Station. The proposed Project's purpose is to provide fuel gas to a planned cogeneration power plant and fuel cell power plant that will be located in close proximity to the Switchgrass Meter Station and will provide power to industrial customers to be located within the boundary of an industrial park. The estimated cost for the project is \$57,300,000; 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 Eryn Pullin, Manager, Regulatory Affairs, Tallgrass Energy, LP, 9 Greenway Plaza Drive, Suite 1100, Houston, Texas 77046, by phone at (713) 997–3932, or by email at eryn.pullin@tallgrass.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 January 20, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for

rehearing, contact the Office of Public Participation (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 5:00 p.m. Eastern Time on January 20, 2026. 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 5:00 p.m. Eastern Time on January 20, 2026. 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 5:00 p.m. Eastern Time on January 20, 2026. 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 CP26–28–000 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 CP26–28–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy

Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, 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: Eryn Pullin, Manager, Regulatory Affairs, Tallgrass Energy, LP, 9 Greenway Plaza Drive, Suite 1100, Houston, Texas 77046, or by email (with a link to the document) at eryn.pullin@tallgrass.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 OPP at (202) 502–6595 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: November 21, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21328 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL26–6–000]

Puget Sound Energy, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On November 24, 2025, the Commission issued an order in Docket

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.

No. EL26–6–000 pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation to determine whether Puget Sound Energy, Inc.'s market-based rate authority in the Seattle City Light balancing authority area is unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Puget Sound Energy, Inc.*, 193 FERC ¶ 61,161 (2025).

The refund effective date in Docket No. EL26–6–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL26–6–000 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 (2025), within 21 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, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Authority: 18 CFR 2.1.

Dated: November 24, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21485 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26–11–000]

Columbia Gulf Transmission, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Pulaski Project, and Notice of Public Scoping Session

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Pulaski Project involving construction and operation of facilities by Columbia Gulf Transmission, LLC (Columbia) in Lincoln County and Pulaski County, Kentucky. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as "scoping." The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the NEPA Process and Environmental Document section of this notice.

By this notice, the Commission requests public comments on the scope

of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on December 24, 2025. Comments may be submitted in written or oral form. Further details on how to submit comments are provided in the Public Participation section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written or oral comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on October 15, 2025, you will need to file those comments in Docket No. CP26–11–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

Columbia provided landowners with a fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" which addresses typically asked questions, including the use of

eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas, Landowner Topics link.

Public Participation

There are four methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208-3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment

feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; a comment on a particular project is considered a "Comment on a Filing"; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP26-11-000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

(4) In lieu of sending written comments, the Commission invites you to attend one of the public scoping sessions its staff will conduct in the project area, scheduled as follows:

Date and time	Location
Tuesday, December 9, 2025, 6:00–8:00 p.m.	First Southern Veterans Park, 567 Goshen Rd., Stanford, Kentucky 40484, 606–235–0462.
Wednesday, December 10, 2025, 6:00–8:00 p.m.	The Center for Rural Development, 2292 S Highway 27, Somerset, Kentucky 42501, 606–677–6000.

The primary goal of these scoping sessions is to have you identify the specific environmental issues and concerns that should be considered in the environmental document. Individual oral comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of oral comments in a convenient way during the timeframe allotted.

Each scoping session is scheduled from 6:00 p.m. to 8:00 p.m. Eastern Standard Time. You may arrive at any time after 6:00 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival. Comments will be taken until 8:00 p.m. However, if no additional numbers have been handed out and all individuals who wish to provide comments have had an opportunity to do so, staff may conclude the session at 7:30 p.m. Please see appendix 1 for additional information on the session format and conduct.¹

Your oral comments will be recorded by a court reporter (with FERC staff or representative present) and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system (see the last

page of this notice for instructions on using eLibrary). If a significant number of people are interested in providing oral comments in the one-on-one settings, a time limit of 5 minutes may be implemented for each commentor. Although there will not be a formal presentation, Commission staff will be available throughout the scoping session to answer your questions about the environmental review process. Representatives from Columbia will also be present to answer project-specific questions.

It is important to note that the Commission provides equal consideration to all comments received, whether filed in written form or provided orally at a scoping session.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

Summary of the Proposed Project

Columbia proposes to install and operate 41.3 miles of new 30-inch-

diameter greenfield natural gas pipeline from Lincoln County Kentucky to the new South Somerset Delivery Meter Station located in Pulaski County, Kentucky, with additional aboveground facilities. The Pulaski Project would provide about 253 million standard cubic feet of natural gas per day to the John S. Cooper Power Station in Pulaski County, Kentucky. According to Columbia, its project would service its new and existing generation resources.

The Pulaski Project would consist of the following facilities:

- 41.3 miles of new 30-inch-diameter greenfield natural gas pipeline;
- a proposed tie-in to the Columbia Mainline in Lincoln County, Kentucky, including a new launcher/receiver and bidirectional pig² trap;
- a new meter and regulator station designated as the South Somerset Delivery Meter Station in Pulaski County, Kentucky, including a tie-in to East Kentucky Power Cooperative's (EKPC's) John S. Cooper Power Station, a new launcher/receiver, and a bidirectional pig trap; and
- four new mainline valves.

The general location of the project facilities is shown in appendix 3.

Land Requirements for Construction

Construction of the proposed facilities would disturb about 657.2 acres of land for the aboveground facilities and the pipeline. Following construction, Columbia would maintain about 254.0

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary." For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at FercOnlineSupport@ferc.gov or call toll free, (866) 208-3676 or TTY (202) 502-8659.

² A "pig" is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

acres for permanent operation of the project's facilities; the remaining acreage would be restored and revert to former uses. About 27 percent of the proposed pipeline route parallels existing EKPC and/or Kentucky Utilities Company rights-of-way.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed project under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomics;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary³ and the

Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.⁴ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.⁵ The environmental document for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the

analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number CP26–11–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached "Mailing List Update Form" (appendix 2).

Additional Information

Additional information about the project is available from the FERC website at www.ferc.gov using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number in the "Docket Number" field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

Authority: 18 CFR 2.1.

Dated: November 24, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21487 Filed 11–26–25; 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:

⁴ Cooperating agency responsibilities are addressed in Section 107(a)(3) of NEPA (42 U.S.C. 4336(a)(3)).

⁵ The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

³ For instructions on connecting to eLibrary, refer to the last page of this notice.

Filings Instituting Proceedings

Docket Numbers: PR26–16–000.
Applicants: NorthWestern Energy Public Service Corporation.
Description: 284.123 Rate Filing: Revised Statement of Operating Conditions to be effective 11/1/2025.
Filed Date: 11/20/25.
Accession Number: 20251120–5254.
Comment Date: 5 p.m. ET 12/11/25.
Docket Numbers: RP26–221–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Compliance filing: Cashout Report 2024–2025 to be effective N/A.
Filed Date: 11/20/25.
Accession Number: 20251120–5141.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–222–000.
Applicants: Adelphia Gateway, LLC.
Description: 4(d) Rate Filing: Adelphia Gateway NCA–NRA Filing to be effective 1/1/2026.
Filed Date: 11/20/25.
Accession Number: 20251120–5163.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–223–000.
Applicants: Crossroads Pipeline Company LLC.
Description: 4(d) Rate Filing: XRD—Citadel NR Agmt 318203, Eff. 12.1.25 to be effective 12/1/2025.
Filed Date: 11/20/25.
Accession Number: 20251120–5177.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–224–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: 4(d) Rate Filing: Article 11.2(a) Inflation Adjustment Filing 2026 to be effective 1/1/2026.
Filed Date: 11/20/25.
Accession Number: 20251120–5216.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–225–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: 4(d) Rate Filing: Amended NRAs—TECO and PGS to be effective 12/1/2025.
Filed Date: 11/21/25.
Accession Number: 20251121–5085.
Comment Date: 5 p.m. ET 12/3/25.
Docket Numbers: RP26–226–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: 4(d) Rate Filing: List of Non-Conforming Service Agreements (AGC et al) to be effective 12/22/2025.
Filed Date: 11/21/25.
Accession Number: 20251121–5158.
Comment Date: 5 p.m. ET 12/3/25.

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: RP24–781–011.
Applicants: Algonquin Gas Transmission, LLC.
Description: Compliance filing: AGT New York Delivery Surcharge 2025 Filing to be effective 1/1/2026.
Filed Date: 11/20/25.
Accession Number: 20251120–5196.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–34–001.
Applicants: Egan Hub Storage, LLC.
Description: Compliance filing: Egan—FOSA Ratchet Compliance Filing to be effective 11/1/2025.
Filed Date: 11/21/25.
Accession Number: 20251121–5069.
Comment Date: 5 p.m. ET 12/3/25.
Docket Numbers: RP26–35–001.
Applicants: Bobcat Gas Storage.
Description: Compliance filing: Bobcat—FOSA Ratchets Compliance Filing to be effective 11/1/2025.
Filed Date: 11/21/25.
Accession Number: 20251121–5071.
Comment Date: 5 p.m. ET 12/3/25.
Docket Numbers: RP26–45–001.
Applicants: UGI Mt. Bethel Pipeline, LLC.
Description: Compliance filing: Amend Order No. 587–AA Compliance Filing (RP26–45–) to be effective 8/1/2025.
Filed Date: 11/20/25.
Accession Number: 20251120–5167.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–46–001.
Applicants: UGI Storage Company.
Description: Compliance filing: Amend Order No. 587–AA Compliance Filing (RP26–46–) to be effective 8/1/2025.
Filed Date: 11/20/25.
Accession Number: 20251120–5161.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–47–001.
Applicants: UGI LNG Inc.
Description: Compliance filing: Amend Order No. 587–AA Compliance Filing (RP26–47–) to be effective 8/1/2025.
Filed Date: 11/20/25.
Accession Number: 20251120–5173.
Comment Date: 5 p.m. ET 12/2/25.
Docket Numbers: RP26–48–001.
Applicants: UGI Sunbury, LLC.
Description: Compliance filing: Amend Order No. 587–AA Compliance Filing (RP26–48–) to be effective 8/1/2025.

Filed Date: 11/20/25.

Accession Number: 20251120–5149.

Comment Date: 5 p.m. ET 12/2/25.

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/fercensearch.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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: November 21, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–21330 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. CP26–20–000]

Columbia Gas Transmission, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on November 13, 2025, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed an application under section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations requesting authorization for its Southeast Virginia Energy Storage Project (Project) consisting of the construction of an approximately 1.3 billion cubic feet liquified natural gas storage tank system, associated liquefaction and vaporization facilities, approximately 5,398 feet of 12-inch-diameter pipeline, and other appurtenant facilities located in Sussex County, Virginia. The Project facilities will provide up to 1,100,000 dekatherms per day of new commercial storage capacity, designed to meet winter peak-day load requirements, mitigate pricing volatility during high-demand periods, and enhance energy

reliability. Columbia also proposes to establish a new firm liquefaction storage service under Rate Schedule FLS. Columbia estimates the total cost of the Project to be \$384,184,996,^{1 2} all as more fully set forth in the application which is on file with the Commission and open for 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 regarding the proposed project should be directed to David A. Alonzo, Manager, Project Authorizations, Columbia Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas, 77002-2700, by phone at (832) 320-5477, or by email at david_alonzo@tcenergy.com.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,³ within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other

milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Water Quality Certification

Columbia stated a water quality certificate under section 401 of the Clean Water Act is required for the project from Virginia Department of Environmental Quality—Water Division. When available, Columbia should submit to the Commission a copy of the request for certification for the Commission authorization, including the date the request was submitted to the certifying agency, and either (1) a copy of the certifying agency's decision or (2) evidence of waiver of water quality certification.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 15, 2025. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)⁴ and 385.211⁵ of the Commission's

regulations under the NGA, any person⁶ may file a protest to the application. Protests must comply with the requirements specified in section 385.2001⁷ of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on December 15, 2025.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP26-20-000 in your submission.

(1) 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;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Comment on a Filing"; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP26-20-000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will

¹ Liquefaction Contract Quantity represents the firm quantity of liquified natural gas that a customer may store under the terms of the service agreement. Columbia states the LCQ will be subject to an incremental capacity rate reflecting the cost of the liquefaction infrastructure and associated operations.

² Maximum Daily Withdrawal Deliverability Quantity defines the firm daily quantity of LNG that a customer may withdraw from storage and redeliver into Columbia's pipeline system. Columbia states the MDWDQ will be subject to a demand rate that reflects the cost of maintaining withdrawal deliverability and storage integrity

³ 18 CFR 157.9.

⁴ 18 CFR 157.10(a)(4).

⁵ 18 CFR 385.211.

⁶ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁷ 18 CFR 385.2001.

receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, 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. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,⁸ 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 Procedure⁹ and the regulations under the NGA¹⁰ by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on December 15, 2025. 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>.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP26–20–000 in your submission.

(1) You may file your motion to intervene 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 "Intervention." The eFiling feature

includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP26–20–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (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: David A. Alonzo, Manager, Project Authorizations, Columbia Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas, 77002–2700, by email (with a link to the document) at david_alonzo@tcenergy.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. Service can be via email with a link to the document.

All timely, unopposed¹¹ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹² 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.¹³ 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.

Tracking the Proceeding

Throughout the proceeding, additional information about the project

will be available from OPP at (202) 502–6595 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.

Intervention Deadline: 5:00 p.m.

Eastern Time on December 15, 2025.

Authority: 18 CFR 2.1.

Dated: November 24, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–21488 Filed 11–26–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2587–066]

Northern States Power Company; Notice Of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a new license to continue to operate and maintain the Superior Falls Hydroelectric Project No. 2587 (project). The project is located on the Montreal River in Gogebic County, Michigan, and Iron County, Wisconsin. Commission staff has prepared an Environmental Assessment (EA) for the project.¹

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1734709056.

⁸ 18 CFR 385.102(d).

⁹ 18 CFR 385.214.

¹⁰ 18 CFR 157.10.

¹¹ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹² 18 CFR 385.214(c)(1).

¹³ 18 CFR 385.214(b)(3) and (d).

The Commission provides all interested persons with an opportunity to view and/or print the EA 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. For assistance, contact FERC Online Support at FEROnlineSupport@ferc.gov, or at (866) 208-3676 (toll-free), or (202) 502-8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/FEROnline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed on or before 5:00 p.m. Eastern Time on December 24, 2025.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. Commenters can submit brief comments up to 10,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. For assistance, please contact FERC Online Support. 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, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-2587-066.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

For further information, contact Nicholas Ettema by telephone at (312) 596-4447 or by email at nicholas.ettema@ferc.gov.

Authority: 18 CFR 2.1.

Dated: November 24, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-21484 Filed 11-26-25; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2610-012]

Northern States Power Company; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a subsequent license to continue to operate and maintain the Saxon Falls Hydroelectric Project No. 2610 (project). The project is located on the Montreal River in Gogebic County, Michigan, and Iron County, Wisconsin. Commission staff has prepared an Environmental Assessment (EA) for the project.¹

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA 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. For assistance, contact FERC Online Support at FEROnlineSupport@ferc.gov, or at (866) 208-3676 (toll-free), or (202) 502-8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/FEROnline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed on or before 5:00 p.m. Eastern Time on December 24, 2025.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. Commenters can submit brief comments up to 10,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>.

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1734709041.

ferconline.ferc.gov/QuickComment.aspx. For assistance, please contact FERC Online Support. 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, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-2610-012.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502-6595 or OPP@ferc.gov.

For further information, contact Nicholas Ettema by telephone at (312) 596-4447 or by email at nicholas.ettema@ferc.gov.
Authority: 18 CFR 2.1.

Dated: November 24, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025-21486 Filed 11-26-25; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 12913-01-OW]

Notice of Funding Availability for Credit Assistance Under the Water Infrastructure Finance and Innovation Act (WIFIA) Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of funding availability.

SUMMARY: The purpose of this notice of funding availability (NOFA) is to solicit letters of interest (LOIs) from prospective borrowers seeking credit assistance from the U.S. Environmental Protection Agency (EPA) under the Water Infrastructure Finance and Innovation Act (WIFIA) program. EPA estimates that it may lend approximately \$6.5 billion to help finance \$13 billion in water infrastructure investment.

DATES: LOIs submitted on or after December 29, 2025 will be reviewed using the scoring criteria outlined in this NOFA.

ADDRESSES: Prospective borrowers should submit all LOIs electronically via EPA's SharePoint site. To be granted

access to the SharePoint site, prospective borrowers should contact wifia@epa.gov and request a link to the SharePoint site, where they can securely upload their LOIs and then email wifia@epa.gov once the complete LOI package has been uploaded to the SharePoint site. EPA will notify prospective borrowers that their LOI has been received via a confirmation email.

Prospective borrowers can access additional information, including the WIFIA program handbook and application materials, on the WIFIA website: <https://www.epa.gov/wifia/>.

FOR FURTHER INFORMATION CONTACT: Dallas Shattuck, Office of Water, Environmental Protection Agency; telephone number: (202) 564-0972; or email: shattuck.dallas@epa.gov (preferred).

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
- II. Program Funding
- III. Eligibility Requirements
- IV. Budgetary Scoring Determination for Non-Federal Projects
- V. Type and Amount of Credit Assistance
- VI. Letters of Interest and Applications
- VII. Cost
- VIII. Selection Criteria
- IX. Federal Requirements
- X. Opportunities to Learn More About the WIFIA Program

I. Background

Congress enacted the Water Infrastructure Finance and Innovation Act (WIFIA) as part of the Water Resources Reform and Development Act of 2014 (WRRDA). Codified at 33 U.S.C. 3901–3915, WIFIA authorizes a Federal credit program for water infrastructure projects to be administered by EPA. WIFIA authorizes EPA to provide Federal credit assistance in the form of secured (direct) loans or loan guarantees for eligible water infrastructure projects.

The WIFIA program's mission is to accelerate investment in our nation's water, wastewater, and stormwater infrastructure by providing long-term, low-cost, supplemental credit assistance under customized terms to creditworthy water infrastructure projects of national and regional significance. For this NOFA, the WIFIA program is implementing five key priorities that align with the WIFIA statute and EPA's "Powering the Great American Comeback" Initiative:

A. Providing Safe Drinking Water and Improving Water Quality

To further EPA's mission, projects should protect human health and/or the environment. Project types are wide-

ranging and include, but are not limited to, projects that: improve water quality, support compliance with drinking water standards and wastewater permit requirements, reduce stormwater runoff, modernize aging water infrastructure, address PFAS and other emerging contaminants, and remove lead service lines. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(F)(ii) (Selection Criteria Category: Project Impact (ii)—"Helps maintain or protect the environment"), and EPA's "Powering the Great American Comeback" Initiative—Pillar 1: Clean Air, Land, and Water for Every American.

B. Pursuing Energy Independence, Exploration, Development, or Production

EPA encourages the submission of projects that serve populations in regions impacted by significant energy exploration, development, or production. These projects can help communities pursue energy independence and lower energy costs for communities. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(G) (Selection Criteria Category: Project Impact (iii)—"Energy exploration, development, or production areas") and EPA's "Powering the Great American Comeback" Initiative—Pillar 2: Restore American Energy Dominance.

C. Advancing Local, Regional, and State Water Priorities

Localities, regions, and states understand their specific water challenges and priorities. EPA will partner with localities, regions, and states across the country to advance durable water infrastructure projects that address the critical needs of all communities, especially for small and rural communities. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(I) (Selection Criteria Category: Project Impact (v)—"Identified municipal, state, or regional priorities") and EPA's "Powering the Great American Comeback" Initiative—Pillar 3: Permitting Reform, Cooperative Federalism, and Cross-Agency Partnership.

D. Supporting Water Sector Innovation

EPA is prioritizing projects that incorporate new or innovative technology, which can play a significant role in helping states, tribes, and communities ensure the provision of clean, safe, and reliable water supplies. In particular, water reuse technology solves a variety of water challenges, such as expanding water resources to

support economic development (e.g., artificial intelligence data centers) and alleviating the effects of drought. Other examples of new or innovative technology include, but are not limited to, desalination and cybersecurity enhancements. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(D) (Selection Criteria Category: Project Impact (vi)—"New or innovative approaches") and EPA's "Powering the Great American Comeback" Initiative—Pillar 4: Make the United States the Artificial Intelligence Capital of the World.

E. Promoting Economic Growth for American Industries

Reliable water infrastructure not only benefits residents, but also companies that depend on water resources to maintain and expand operations. Without durable water supplies, American industries, including the automotive, electronic, mining, and artificial intelligence sectors, cannot thrive. EPA encourages prospective borrowers to demonstrate how projects will generate economic and public benefits, such as supporting international commerce, increasing domestic manufacturing, or accelerating economic growth. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(A)(iv) (Selection Criteria Category: Project Impact (i)—"Generation of economic and public benefits") and EPA's "Powering the Great American Comeback" Initiative—Pillar 5: Protecting and Bringing Back American Auto Jobs.

II. Program Funding

A. WIFIA Program Appropriation

Congress appropriated \$59.6 million in funding to cover the subsidy cost of providing WIFIA credit assistance. EPA estimates this appropriation will allow the Agency to provide approximately \$6.5 billion¹ in long-term, low-cost financing to water infrastructure projects and accelerate approximately \$13 billion in infrastructure investment around the country.

B. Funding Availability Period

LOIs may be submitted by prospective borrowers and will be reviewed by EPA on a rolling basis. LOIs shall be submitted using the LOI form found at <https://www.epa.gov/wifia>. LOIs will be

¹ This estimated loan volume is provided for reference only. Consistent with the Federal Credit Reform Act of 1990 and the requirements of the Office of Management and Budget, the actual subsidy cost of providing credit assistance is based on individual project characteristics and calculated on a project-by-project basis. Thus, actual lending capacity may vary.

reviewed based on the scoring guide applicable at the time of submission. The publication of this NOFA does not impact LOIs previously submitted to EPA, which continue to be reviewed based on the applicable requirements at the time of submission.

LOIs submitted on or after December 29, 2025, will be reviewed using the scoring criteria outlined in this NOFA. This NOFA provides guidance on all WIFIA funding authority available, including funding from previous years. Any funding authority not obligated in the fiscal year for which it is authorized remains available for obligation in subsequent years.

III. Eligibility Requirements

The WIFIA statute and implementing rules provide eligibility requirements for prospective borrowers, projects, and project costs. In general, the WIFIA program can provide loans to public and private borrowers for a wide variety of water infrastructure projects. Detailed information on WIFIA eligibility requirements for prospective borrowers, projects, and project costs can be found in the WIFIA program handbook at <https://www.epa.gov/wifia/wifia-program-handbook>.

A. Eligible Applicants

Prospective borrowers must be an eligible entity to receive WIFIA credit assistance. Eligible entities include: corporations, partnerships, joint ventures and trusts; state, local, and tribal governments; and state infrastructure financing authorities.

Public sponsorship is required for projects undertaken by an entity that is not a state or local government or agency or instrumentality of a state or local government, or a tribal government or consortium of tribal governments.

B. Eligible Projects

The WIFIA statute authorizes EPA to provide credit assistance for a wide variety of creditworthy drinking water, wastewater, and stormwater infrastructure projects. The non-exhaustive list below includes several examples of projects eligible for WIFIA credit assistance. For detailed project eligibility information, review the WIFIA program handbook at <https://www.epa.gov/wifia/wifia-program-handbook>.

- A wide range of wastewater, stormwater, and nonpoint source projects that are eligible under the Clean Water State Revolving Fund (CWSRF). More detailed CWSRF eligibility information can be found at <https://www.epa.gov/cwsrf>;

- A wide range of drinking water infrastructure projects—including treatment, transmission and distribution, source, storage, consolidation/partnerships, and the creation of new systems—that are eligible under the Drinking Water State Revolving Fund (DWSRF). More detailed DWSRF eligibility information can be found at <https://www.epa.gov/dwsrf>;

- Repair, rehabilitation, or replacement of drinking water, wastewater, or stormwater infrastructure;

- Enhanced energy efficiency in the operation of a public water system or publicly owned treatment works;

- Desalination, aquifer storage and recovery, water recycling, or other projects to provide an alternative water supply and reduce aquifer depletion;

- Drought prevention, reduction, or mitigation projects;

- Acquisition of real property or an interest in real property, in certain circumstances;

- A combination of drinking water and wastewater projects submitted by a state infrastructure financing authority; and

- A combination of eligible projects, secured by a common security pledge, for which a single entity, or a combination of eligible entities, submits a single application.

C. Eligible Costs

Eligible project costs are costs associated with the following activities:

- (i) Development-phase activities, including planning, feasibility analysis (including any related analysis necessary to carry out an eligible project), revenue forecasting, environmental review, permitting, preliminary engineering and design work, and other preconstruction activities;

- (ii) Construction, reconstruction, rehabilitation, and replacement activities;

- (iii) The acquisition of real property or an interest in real property (including water rights, land relating to the project, and improvements to land), environmental mitigation, construction contingencies and acquisition of equipment; and

- (iv) Capitalized interest necessary to meet market requirements, reasonably required reserve funds, capital issuance expenses, and other carrying costs during construction. Capitalized interest on WIFIA credit assistance may not be included as an eligible project cost.

IV. Budgetary Scoring Determination for Non-Federal Projects

To comply with Public Law 116–260, a project selected for WIFIA financing will be assessed using two initial screening questions and sixteen scoring factors. These questions will help the Office of Management and Budget (OMB) determine compliance with budgetary scoring rules, a process that will be conducted in parallel to EPA's LOI evaluation process outlined in this NOFA. The questions may be found in **Federal Register** publication titled “Water Infrastructure Finance and Innovation Act Program (WIFIA) Criteria Pursuant to the Further Consolidated Appropriations Act, 2020” (85 FR 39189, June 30, 2020). EPA encourages project applicants to review the scoring criteria and provide sufficient information in the LOI or as an attachment to the LOI to facilitate EPA and OMB review of the prospective project considering the scoring criteria.

V. Type and Amount of Credit Assistance

Under this NOFA, EPA will provide credit assistance in the form of direct loans or loan guarantees. Each prospective borrower should list the estimated total capital costs of the project broken down by activity type.

A. Minimum Project Costs

Projects must have eligible costs that are reasonably anticipated to be equal to or exceed \$20 million, or for small communities (serving not more than 25,000 individuals), project costs that are reasonably anticipated to equal or exceed \$5 million.

B. Maximum Amount of WIFIA Credit Assistance

The maximum amount of WIFIA credit assistance to a project is 49 percent of eligible project costs in almost all instances. For small communities who face significant water infrastructure challenges and economic or administrative hardship accessing funding and financing, the WIFIA program may provide credit assistance up to a maximum of 80 percent of eligible project costs.

C. Appropriation Set-Aside for Small Communities

EPA will endeavor to use 15 percent of its budget authority for small communities. Recognizing the need that exists in both small and large communities to invest in infrastructure, the WIFIA statute requires that EPA set aside 15 percent of the budget authority appropriated each year for small communities, defined as systems that

serve a population of 25,000 or less. Of the funds set aside, any amount not obligated by June 1 of the fiscal year for which budget authority is set aside may be used for any size community.

VI. Letters of Interest and Applications

Each prospective borrower will be required to submit an LOI and, if invited, an application to EPA to be considered for approval. This section describes the LOI submission and application submission.

A. Letter of Interest (LOI)

Prospective borrowers seeking a WIFIA loan must submit an LOI describing the project fundamentals and addressing the WIFIA selection criteria. Prospective borrowers can find more information on the LOI at <https://www.epa.gov/wifia>.

The primary purpose of the LOI is to provide adequate information to EPA to: (i) determine the eligibility of the prospective borrower and the prospective project, (ii) perform a preliminary creditworthiness assessment, (iii) perform a preliminary engineering feasibility assessment, and (iv) evaluate the project against the selection criteria. Based on its review of the information provided in the LOI, EPA will invite prospective borrowers to submit applications for their projects. Prospective borrowers are encouraged to review the WIFIA program handbook at <https://www.epa.gov/wifia/wifia-program-handbook> to help create the best justification possible for the project and a cohesive and comprehensive LOI submittal.

Prospective borrowers must utilize the WIFIA LOI form and follow the guidelines contained on the WIFIA program website: <https://www.epa.gov/wifia>. Prospective borrowers should provide the LOI and any attachments as Microsoft Word documents or searchable PDF files, whenever possible, to facilitate EPA's review. Additionally, prospective borrowers must ensure that financial information, including the pro forma financial statement, is in a formula-based Microsoft Excel document. Prospective borrowers should provide sufficient detail about the project for EPA's review. EPA will notify a prospective borrower if its project is deemed ineligible as described in section III of this document or if additional information is needed to assess the LOI package.

B. Application

After EPA concludes its evaluation of a complete LOI package, a selection committee will invite the prospective borrower to apply based on review and

scoring, as applicable, of the selection criteria and satisfaction of the eligibility requirements. The selection committee may choose to combine multiple LOIs or separate projects from a prospective borrower based on the creditworthiness review and may offer an alternative amount of WIFIA assistance than requested in the LOI. Final applications should be received by EPA within 365 days of the invitation to apply, but EPA may extend the deadline on a case-by-case basis if the LOI schedule signals additional time may be needed.

An invitation to apply for WIFIA credit assistance does not guarantee EPA's approval, which remains subject to a project's continued eligibility, including creditworthiness, the successful negotiation of terms acceptable to EPA, and the availability of funds at the time at which all necessary recommendations and evaluations have been completed. However, the purpose of EPA's LOI review is to pre-screen prospective borrowers to the extent practicable. It is expected that EPA will only invite prospective borrowers to apply if it anticipates that those prospective borrowers are able to obtain WIFIA credit assistance. Detailed information needs for the application are listed in the application form at <https://www.epa.gov/wifia> and described in the WIFIA program handbook.

VII. Cost

There is no cost to submit an LOI. For information about application, closing, and post-closing costs, please refer to the WIFIA program handbook.

VIII. Selection Criteria

This section specifies the criteria and process that EPA will use to evaluate LOIs and award applications for WIFIA assistance.

EPA will evaluate and select proposed projects described in the LOIs using the selection criteria established in the statute and regulation, and the Administration priorities identified in section I of this document. EPA's priorities reflect water sector challenges that require innovative tools to assist borrowers in managing and adapting to our most pressing public health and environmental challenges. These priorities are reflected in the scoring methodology of the selection criteria below and described in greater detail in the WIFIA program handbook.

The WIFIA selection criteria are divided into three categories: Project Readiness, Borrower Creditworthiness, and Project Impact. Each LOI will be evaluated for the extent to which the project satisfies the criteria listed below

for each category. To satisfy the overall category review, it is not necessary to satisfy all criteria for each category. For the Project Impact category, WIFIA staff will score LOIs based on the points indicated below and compare the cumulative score received to a minimum scoring threshold. All projects that satisfy category-level review for all three categories, including exceeding the minimum scoring threshold, will be selected for funding, assuming sufficient funds are still available. The criteria are as follows:

Project Readiness

(i) The readiness of the project to proceed toward development, including a demonstration by the obligor that there is a reasonable expectation that the contracting process for construction of the project can commence by not later than 90 days after the date on which a Federal credit instrument is obligated for the project under WIFIA. 33 U.S.C. 3907(b)(2)(J).

(ii) Preliminary engineering feasibility analysis. 33 U.S.C. 3907(a)(2); 33 U.S.C. 3907(a)(6).

Borrower Creditworthiness

(i) The likelihood that assistance under WIFIA would enable the project to proceed at an earlier date than the project would otherwise be able to proceed. 33 U.S.C. 3907(b)(2)(C).

(ii) The extent to which the project financing plan includes public or private financing in addition to assistance under WIFIA. 33 U.S.C. 3907(b)(2)(B).

(iii) The extent to which assistance under WIFIA reduces the contribution of Federal assistance to the project. 33 U.S.C. 3907(b)(2)(K).

(iv) The amount of budget authority required to fund the Federal credit instrument made available under WIFIA. 33 U.S.C. 3907(b)(2)(E).

(v) Preliminary determination of prospective borrower and project creditworthiness. 33 U.S.C. 3907(a)(1).

Project Impact

(i) *15 points:* The extent to which the project is nationally or regionally significant, with respect to the generation of economic and public benefits, such as (1) the reduction of flood risk; (2) the improvement of water quality and quantity, including aquifer recharge; (3) the protection of drinking water, including source water protection; and (4) the support of international commerce. 33 U.S.C. 3907(b)(2)(A).

(ii) *15 points:* The extent to which the project (1) protects against extreme weather events, such as floods or

hurricanes; or (2) helps maintain or protect the environment. 33 U.S.C. 3907(b)(2)(F).

(iii) *15 points*: The extent to which the project serves regions with significant energy exploration, development, or production areas. 33 U.S.C. 3907(b)(2)(G).

(iv) *10 points*: The extent to which a project serves regions with significant water resource challenges, including the need to address: (1) water quality concerns in areas of regional, national, or international significance; (2) water quantity concerns related to groundwater, surface water, or other water sources; (3) significant flood risk; (4) water resource challenges identified in existing regional, state, or multistate agreements; or (5) water resources with exceptional recreational value or ecological importance. 33 U.S.C. 3907(b)(2)(H).

(v) *10 points*: The extent to which the project addresses identified municipal, state, or regional priorities. 33 U.S.C. 3907(b)(2)(I).

(vi) *15 points*: The extent to which the project uses new or innovative approaches. 33 U.S.C. 3907(b)(2)(D).

(vii) *5 points*: The extent to which the project addresses needs for repair, rehabilitation or replacement of a treatment works, community water system, or aging water distribution or wastewater collection system. 40 CFR 35.10055(a)(12).

(viii) *5 points*: The extent to which the project serves economically stressed communities, or pockets of economically stressed rate payers within otherwise non-economically stressed communities. 40 CFR 35.10055(a)(13).

(ix) *10 points*: The extent to which the project reduces exposure to lead in the nation's drinking water systems or addresses emergent contaminants. 40 CFR 35.10055(b).

The scoring scales and guidance used to evaluate each project against the selection criteria are available in the WIFIA program handbook. Prospective borrowers considering WIFIA financing should review the WIFIA program handbook and discuss how the project addresses each of the selection criteria in the LOI submission.

IX. Federal Requirements

All projects receiving WIFIA assistance must comply with applicable Federal requirements. Compliance with Federal requirements is not required for submitting a letter of interest, being invited to apply for a WIFIA loan, or submitting an application. The WIFIA program will review selected projects for compliance with Federal

requirements once they have submitted an application. Additional information about Federal compliance requirements is available in the WIFIA program handbook and at <https://www.epa.gov/wifia/wifia-federal-compliance-requirements>.

X. Opportunities To Learn More About the WIFIA Program

EPA hosts regular outreach events and monthly office hours to provide further information about submitting an LOI. The outreach schedule and registration instructions can be found on the WIFIA program website: www.epa.gov/wifia.

Prospective borrowers with questions about the program or interest in meeting with the WIFIA program staff may send a request to wifia@epa.gov. EPA will meet with all prospective borrowers interested in discussing the program prior to submission of an LOI.

Authority: 33 U.S.C. 3901–3915; 40 CFR part 35.

Jessica L. Kramer,
Assistant Administrator.

[FR Doc. 2025–21446 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 12914–01–OW]

Notice of Funding Availability for Credit Assistance Under the State Infrastructure Financing Authority Water Infrastructure Finance and Innovation Act (SWIFIA) Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of funding availability.

SUMMARY: The purpose of this notice of funding availability (NOFA) is to solicit letters of interest (LOIs) from prospective state infrastructure financing authority borrowers seeking credit assistance from the U.S. Environmental Protection Agency (EPA) under the State Infrastructure Financing Authority Water Infrastructure Finance and Innovation Act (SWIFIA) program. EPA's SWIFIA program is managed by the WIFIA division and operates under the authority of the WIFIA statute. EPA estimates that it may lend approximately \$550 million to help finance over \$1 billion in water infrastructure investment to state infrastructure financing authority borrowers.

DATES: LOIs submitted on or after December 29, 2025 will be reviewed using the scoring criteria outlined in this NOFA.

ADDRESSES: Prospective borrowers should submit all LOIs electronically via EPA's SharePoint site. To be granted access to the SharePoint site, prospective borrowers should contact wifia@epa.gov and request a link to the SharePoint site, where they can securely upload their LOIs and then email wifia@epa.gov once the complete LOI package has been uploaded to the SharePoint site. EPA will notify prospective borrowers that their LOI has been received via a confirmation email.

Prospective borrowers can access additional information, including the SWIFIA program handbook and application materials, on the WIFIA website: <https://www.epa.gov/wifia/wifia-state-revolving-fund-borrowers>.

FOR FURTHER INFORMATION CONTACT:

Dallas Shattuck, Office of Water, Environmental Protection Agency; telephone number: (202) 564–0972; or email: shattuck.dallas@epa.gov (preferred).

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
- II. Program Funding
- III. Eligibility Requirements
- IV. Budgetary Scoring Determination for Non-Federal Projects
- V. Types and Amount of Credit Assistance
- VI. Letters of Interest and Applications
- VII. Cost
- VIII. Selection Criteria
- IX. Federal Requirements
- X. Opportunities to Learn More About the SWIFIA Program

I. Background

Congress enacted the Water Infrastructure Finance and Innovation Act (WIFIA) as part of the Water Resources Reform and Development Act of 2014 (WRRDA). Codified at 33 U.S.C. 3901–3915, WIFIA authorizes a Federal credit program for water infrastructure projects to be administered by EPA. WIFIA authorizes EPA to provide Federal credit assistance in the form of secured (direct) loans or loan guarantees for eligible water infrastructure projects.

Congress amended WIFIA in America's Water Infrastructure Act of 2018 (AWIA) to authorize Federal credit assistance exclusively for state infrastructure financing authority borrowers, commonly referred to as the SWIFIA program.

The SWIFIA program's mission is to accelerate investment in our nation's water, wastewater, and stormwater infrastructure by providing long-term, low-cost, supplemental credit assistance under customized terms to creditworthy water infrastructure projects of national and regional significance. For this

SWIFIA NOFA, EPA is implementing five key priorities that align with the WIFIA statute and EPA's "Powering the Great American Comeback" Initiative:

A. Providing Safe Drinking Water and Improving Water Quality

To further EPA's mission, projects should protect human health and/or the environment. Project types are wide-ranging and include, but are not limited to, projects that: improve water quality, support compliance with drinking water standards and wastewater permit requirements, reduce stormwater runoff, modernize aging water infrastructure, address PFAS and other emerging contaminants, and remove lead service lines. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(F)(ii) (Selection Criterion (v))—"Helps maintain or protect the environment"), and EPA's "Powering the Great American Comeback" Initiative—Pillar 1: Clean Air, Land, and Water for Every American.

B. Pursuing Energy Independence, Exploration, Development, or Production

EPA encourages the submission of projects that serve populations in regions impacted by significant energy exploration, development, or production. These projects can help communities pursue energy independence and lower energy costs for communities. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(G) (Selection Criterion (vi))—"Energy exploration, development, or production areas") and EPA's "Powering the Great American Comeback" Initiative—Pillar 2: Restore American Energy Dominance.

C. Advancing Local, Regional, and State Water Priorities

Localities, regions, and states understand their specific water challenges and priorities. EPA will partner with localities, regions, and states across the country to advance durable water infrastructure projects that address the critical needs of all communities, especially for small and rural communities. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(I) (Selection Criterion (viii))—"Identified municipal, state, or regional priorities") and EPA's "Powering the Great American Comeback" Initiative—Pillar 3: Permitting Reform, Cooperative Federalism, and Cross-Agency Partnership.

D. Supporting Water Sector Innovation

EPA is prioritizing projects that incorporate new or innovative

technology, which can play a significant role in helping states, tribes, and communities ensure the provision of clean, safe, and reliable water supplies. In particular, water reuse technology solves a variety of water challenges, such as expanding water resources to support economic development (e.g., artificial intelligence data centers) and alleviating the effects of drought. Other examples of new or innovative technology include, but are not limited to, desalination and cybersecurity enhancements. This priority aligns with the WIFIA statute at 33 U.S.C. 3907(b)(2)(D) (Selection Criterion (iii))—"New or innovative approaches") and EPA's "Powering the Great American Comeback" Initiative—Pillar 4: Make the United States the Artificial Intelligence Capital of the World.

E. Promoting Economic Growth for American Industries

Reliable water infrastructure not only benefits residents, but also companies that depend on water resources to maintain and expand operations. Without durable water supplies, American industries, including the automotive, electronic, mining, and artificial intelligence sectors, cannot thrive. EPA encourages prospective borrowers to demonstrate how projects will support international commerce, increase domestic manufacturing, or accelerate economic growth. This priority aligns with EPA's "Powering the Great American Comeback" Initiative—Pillar 5: Protecting and Bringing Back American Auto Jobs.

II. Program Funding

A. SWIFIA Program Appropriation

Congress appropriated \$5 million in funding to cover the subsidy cost of providing SWIFIA credit assistance. EPA estimates this appropriation will allow the Agency to provide approximately \$550 million¹ in long-term, low-cost financing to water infrastructure projects and accelerate over \$1 billion in infrastructure investment around the country.

B. Funding Availability Period

LOIs may be submitted by prospective borrowers and will be received by EPA on a rolling basis. LOIs shall be submitted using the SWIFIA LOI form found at <https://www.epa.gov/wifia/>

¹ This estimated loan volume is provided for reference only. Consistent with the Federal Credit Reform Act of 1990 and the requirements of the Office of Management and Budget, the actual subsidy cost of providing credit assistance is based on individual project characteristics and calculated on a project-by-project basis. Thus, actual lending capacity may vary.

wifia-state-revolving-fund-borrowers. Under the rolling process, LOIs will continually be reviewed and selected based on available funds. The publication of this NOFA does not impact LOIs previously submitted to EPA, which continue to be reviewed based on the applicable requirements at the time of submission.

LOIs received on or after December 29, 2025, will be evaluated using the scoring criteria outlined in this NOFA. This NOFA provides guidance on all SWIFIA funding authority available, including funding from previous years. Any funding authority not obligated in the fiscal year for which it is authorized remains available for obligation in subsequent years.

III. Eligibility Requirements

The WIFIA statute and implementing rules set forth eligibility requirements for prospective borrowers, projects, and project costs. The requirements outlined below are described in greater detail in the SWIFIA program handbook found at <https://www.epa.gov/wifia/wifia-state-revolving-fund-borrowers>.

A. Eligible Applicants

Prospective borrowers must be a state infrastructure financing authority to be eligible for SWIFIA credit assistance. EPA defines state infrastructure financing authority as the state entity established or designated by the governor of a state to receive a capitalization grant provided by, or otherwise carry out the requirements of, title VI of the Federal Water Pollution Control Act (33 U.S.C. 1381 et. seq.) or section 1452 of the Safe Drinking Water Act (42 U.S.C. 300j–12).

B. Eligible Projects

To be eligible for SWIFIA credit assistance, the SWIFIA project must be a combination of projects, each of which is eligible for assistance under section 603(c) of the Federal Water Pollution Control Act (33 U.S.C. 1383(c)) or section 1452(a)(2) of the Safe Drinking Water Act (42 U.S.C. 300j–12(a)(2)), for which a state infrastructure financing authority submits to the Administrator a single application.

C. Eligible Costs

Eligible project costs are costs associated with the following activities:

(i) Development-phase activities, including planning, feasibility analysis (including any related analysis necessary to carry out an eligible project), revenue forecasting, environmental review, permitting, preliminary engineering and design

work, and other preconstruction activities;

(ii) Construction, reconstruction, rehabilitation, and replacement activities;

(iii) The acquisition of real property or an interest in real property (including water rights, land relating to the project, and improvements to land), environmental mitigation (including acquisitions pursuant to 33 U.S.C. 3905(8)), construction contingencies, and acquisition of equipment; and

(iv) Capitalized interest necessary to meet market requirements, reasonably required reserve funds, capital issuance expenses, and other carrying costs during construction. Capitalized interest on SWIFIA credit assistance may not be included as an eligible project cost.

IV. Budgetary Scoring Determination for Non-Federal Projects

To comply with Public Law 116–260, a project selected for SWIFIA financing will be assessed using two initial screening questions and sixteen scoring factors. These questions will help the Office of Management and Budget (OMB) determine compliance with budgetary scoring rules, a process that will be conducted in parallel to EPA's LOI evaluation process outlined in this NOFA. The questions may be found in the **Federal Register** publication titled "Water Infrastructure Finance and Innovation Act Program (WIFIA) Criteria Pursuant to the Further Consolidated Appropriations Act, 2020" (85 FR 39189, June 30, 2020). EPA encourages project applicants to review the scoring criteria and provide sufficient information in the LOI or as an attachment to the LOI to facilitate EPA and OMB review of the prospective project considering the scoring criteria.

V. Types and Amount of Credit Assistance

Under the SWIFIA program, EPA is offering senior loans, on parity with a state infrastructure financing authority's other senior capital market debt of the same credit quality, to help the state infrastructure financing authority lend to multiple projects throughout the state.

A. Minimum Project Costs

A SWIFIA project must have eligible project costs that are reasonably anticipated to equal or exceed \$20 million.

B. Maximum Amount of SWIFIA Credit Assistance

The maximum amount of SWIFIA credit assistance to a state infrastructure financing authority is 49 percent of

estimated eligible total costs of the eligible projects that are included in the SWIFIA project.

C. SWIFIA Loan Structures

Prospective SWIFIA borrowers may request one of the following loan structures:

(i) EPA accepts the state infrastructure financing authority's existing capital market debt indenture (to the extent the terms are permissible under Federal law and regulation and WIFIA division policies); or

(ii) The state infrastructure financing authority accepts EPA's standard terms. More information on EPA's standard terms is available at www.epa.gov/wifia.

VI. Letters of Interest and Applications

Each prospective borrower will be required to submit an LOI and, if invited, an application to EPA to be considered for approval. This section describes the LOI submission and application submission.

A. Letter of Interest (LOI)

Prospective borrowers seeking a SWIFIA loan must submit an LOI describing the SWIFIA project fundamentals and addressing the SWIFIA selection criteria.

The primary purpose of the LOI is to provide adequate information to EPA to validate the eligibility and creditworthiness of the prospective borrower and the prospective SWIFIA project and determine the extent to which the SWIFIA project meets the statutory selection criteria. Based on its review of the information provided in the LOI, EPA will invite prospective borrowers to submit applications for their projects.

Prospective borrowers should utilize the LOI form on the WIFIA website and ensure that sufficient detail about the project is provided for EPA's review. EPA will notify a prospective borrower if its SWIFIA project is deemed ineligible as described in section III of this document or if additional information is needed to assess the LOI package.

B. Application

After EPA concludes its evaluation of a complete LOI package, a selection committee will invite the prospective borrower to apply based on satisfaction of the eligibility requirements. So long as budget authority remains available, EPA expects that all eligible state infrastructure financing authority prospective borrowers will be invited to apply for a SWIFIA loan.

An invitation to apply for SWIFIA credit assistance does not guarantee

EPA's approval, which remains subject to a project's continued eligibility, including creditworthiness, the successful negotiation of terms acceptable to EPA, and the availability of funds at the time at which all necessary recommendations and evaluations have been completed. However, the purpose of EPA's LOI review is to pre-screen prospective borrowers to the extent practicable. It is expected that EPA will only invite prospective borrowers to apply if it anticipates that those prospective borrowers are able to obtain SWIFIA credit assistance. Detailed information needs for the application are listed in the application form and described in the SWIFIA program handbook: <https://www.epa.gov/wifia/wifia-state-revolving-fund-borrowers>.

VII. Cost

There is no cost to submit an LOI. For information about application, closing, and post-closing costs, please refer to the SWIFIA program handbook: <https://www.epa.gov/wifia/wifia-state-revolving-fund-borrowers>.

VIII. Selection Criteria

This section specifies the criteria and process that EPA will use to evaluate LOIs and award applications for SWIFIA assistance.

The selection criteria described below are the statutory selection criteria for state infrastructure financing authority borrowers. Following its eligibility determination, EPA will determine the extent to which the SWIFIA project meets the statutory selection criteria. For SWIFIA LOIs, EPA conducts a qualitative assessment and compares the statutory selection criteria to the state infrastructure financing authority's project prioritization process, as outlined in the state's Intended Use Plan and other relevant documents. The selection criteria listed in the WIFIA statute are as follows:

(i) The extent to which the project financing plan includes public or private financing in addition to assistance under WIFIA. 33 U.S.C. 3907(b)(2)(B).

(ii) The likelihood that assistance under WIFIA would enable the project to proceed at an earlier date than the project would otherwise be able to proceed. 33 U.S.C. 3907(b)(2)(C).

(iii) The extent to which the project uses new or innovative approaches. 33 U.S.C. 3907(b)(2)(D).

(iv) The amount of budget authority required to fund the Federal credit instrument made available under WIFIA. 33 U.S.C. 3907(b)(2)(E).

(v) The extent to which the project (1) protects against extreme weather events, such as floods or hurricanes; or (2) helps maintain or protect the environment. 33 U.S.C. 3907(b)(2)(F).

(vi) The extent to which the project serves regions with significant energy exploration, development, or production areas. 33 U.S.C. 3907(b)(2)(G).

(vii) The extent to which a project serves regions with significant water resource challenges, including the need to address: (1) water quality concerns in areas of regional, national, or international significance; (2) water quantity concerns related to groundwater, surface water, or other water sources; (3) significant flood risk; (4) water resource challenges identified in existing regional, state, or multistate agreements; or (5) water resources with exceptional recreational value or ecological importance. 33 U.S.C. 3907(b)(2)(H).

(viii) The extent to which the project addresses identified municipal, state, or regional priorities. 33 U.S.C. 3907(b)(2)(I).

(ix) The readiness of the project to proceed toward development, including a demonstration by the obligor that there is a reasonable expectation that the contracting process for construction of the project can commence by not later than 90 days after the date on which a Federal credit instrument is obligated for the project under WIFIA. 33 U.S.C. 3907(b)(2)(J).

(x) The extent to which assistance under WIFIA reduces the contribution of Federal assistance to the project. 33 U.S.C. 3907(b)(2)(K).

IX. Federal Requirements

All projects receiving SWIFIA credit assistance must comply with applicable Federal requirements. Compliance with Federal requirements is not required for submitting a letter of interest, being invited to apply for a loan, or submitting an application. The WIFIA division will review selected projects for compliance with Federal requirements once they have submitted an application. Additional information about Federal compliance requirements is available at <https://www.epa.gov/wifia/wifia-federal-compliance-requirements>.

X. Opportunities To Learn More About the SWIFIA Program

EPA hosts regular outreach events and monthly office hours to provide further information about submitting an LOI. The outreach schedule and registration instructions can be found on the WIFIA website: <https://www.epa.gov/wifia/connect-wifia-program>.

Prospective borrowers with questions about the program or interest in meeting with the WIFIA division staff may send a request to wifia@epa.gov. EPA will meet with all prospective borrowers interested in discussing the program prior to submission of an LOI.

(Authority: 33 U.S.C. 3901–3915; 40 CFR part 35.)

Jessica L. Kramer,
Assistant Administrator.

[FR Doc. 2025–21447 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–199]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–993–3272 or <https://www.epa.gov/nepa>. Weekly receipt of Environmental Impact Statements (EIS) Filed November 17, 2025 10 a.m. EST Through November 21, 2025 10 a.m. EST Pursuant to CEQ Guidance on 42 U.S.C. 4332.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search>.

EIS No. 20250157, Final, FHWA, OR, Hood River White Salmon Interstate Bridge Replacement Project, Contact: Misty Thorsgard 503–316–2557.

EIS No. 20250158, Final, DOE, GA, ADOPTION—GENERIC—Edwin I. Hatch Nuclear Plant Units 1 and 2 License Renewal of Nuclear Plants Supplement 4 to NUREG–437 Altamaha River Appling County GA, Contact: Don Brown 202–913–3477.

The Department of Energy (DOE) has adopted the Nuclear Regulatory Commission's Final EIS No. 20010206 filed 06/07/2001 with the Environmental Protection Agency. The DOE was not a cooperating agency on this project. Therefore, republication of the document is necessary.

EIS No. 20250159, Final, DOE, GA, ADOPTION—GENERIC—License Renewal of Nuclear Plants Supplement 34 to NUREG–1437 Regarding Vogtle Electric Generating Plant Units 1 and 2 (VEGP) near Waynesboro GA, Contact: Don Brown 202–913–3477.

The Department of Energy (DOE) has adopted the Nuclear Regulatory Commission's Final EIS No. 20080522

filed 12/12/2008 with the Environmental Protection Agency. The DOE was not a cooperating agency on this project. Therefore, republication of the document is necessary.

EIS No. 20250160, Final, NRC, WY, Environmental Impact Statement for the Construction Permit Application for Kemmerer Power Station Unit 1: Final Report, Contact: Patricia Vokoun 301–415–3470.

EIS No. 20250161, Draft, BR, NM, Lower San Acacia Reach Improvements Project, Comment Period Ends: 01/12/2026, Contact: David (Sonny) Cooper 505–462–3599.

EIS No. 20250162, Final, TVA, AL, TVA Pumped Storage Hydropower, Review Period Ends: 01/05/2026, Contact: Elizabeth Smith 865–632–3053.

Dated: November 24, 2025.

Nancy Abrams,
Deputy Director, Federal Activities Division.
[FR Doc. 2025–21448 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2018–0012; FRL–13075–01–OLEM]

Agency Information Collection Activities; Proposed Information Collection Request; Comment Request; State Program Adequacy Determination: Municipal Solid Waste Landfills (MSWLFs) and Non-Municipal, Non-Hazardous Waste Disposal Units That Receive Conditionally Exempt Small Quantity Generator (CESQG) Hazardous Waste, EPA ICR No. 1608.10, OMB Control No. 2050–0152

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “State Program Adequacy Determination: Municipal Solid Waste Landfills (MSWLFs) and Non-Municipal, Non-Hazardous Waste Disposal Units that Receive Conditionally Exempt Small Quantity Generator (CESQG) Hazardous Waste” (EPA ICR No. 1608.10, OMB Control No. 2050–0152) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described in **SUPPLEMENTARY**

INFORMATION. This is a proposed extension of the ICR, which is currently approved through June 30, 2026. This document allows 60 days for public comments.

DATES: Comments may be submitted on or before January 27, 2026.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OLEM-2018-0012, to EPA online using <https://www.regulations.gov> (our preferred method), or by mail to: EPA Docket Center, U.S. Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Mail Code 5101T, Washington, DC 20460; telephone number: (202) 566-0453; vyas.peggy@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through June 30, 2026. 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.

This document allows 60 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at <https://www.regulations.gov> or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit <https://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) 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; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate forms of information technology. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** document to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Section 4010(c) of the Resource Conservation and Recovery Act (RCRA) of 1976 requires that EPA revise the landfill criteria promulgated under paragraph (1) of section 4004(a) and section 1008(a)(3). Section 4005(c) of RCRA, as amended by the Hazardous Solid Waste Amendments (HSWA) of 1984, requires states to develop and implement permit programs to ensure that MSWLFs and non-municipal, non-hazardous waste disposal units that receive household hazardous waste or CESQG hazardous waste are in compliance with the revised criteria for the design and operation of non-municipal, non-hazardous waste disposal units under 40 CFR part 257, subpart B and MSWLFs under 40 CFR part 258 (40 CFR part 257, subpart B and 40 CFR part 258 are henceforth referred to as the "revised federal criteria"). Section 4005(c) of RCRA further mandates the EPA Administrator to determine the adequacy of state permit programs to ensure owner and/or operator compliance with the revised federal criteria. A state program that is deemed adequate to ensure compliance may afford flexibility to owners or operators in the approaches they use to meet federal requirements, significantly reducing the burden associated with compliance.

In response to the statutory requirement in section 4005(c) of RCRA, EPA developed 40 CFR part 239, commonly referred to as the State Implementation Rule (SIR). The SIR describes the state application and EPA review procedures and defines the elements of an adequate state permit program.

The collection of information from the state during the permit program adequacy determination process allows EPA to evaluate whether a program for which approval is requested is appropriate in structure and authority to ensure owner or operator compliance with the revised federal criteria. The SIR does not require the use of a particular application form. Section 239.3 of the

SIR, however, requires that all state applications contain the following five components:

(1) A transmittal letter requesting permit program approval.

(2) A narrative description of the state permit program, including a demonstration that the state's standards for non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste are technically comparable to the 40 CFR part 257, subpart B criteria and/or that its MSWLF standards are technically comparable to the 40 CFR part 258 criteria.

(3) A legal certification demonstrating that the state has the authority to carry out the program.

(4) Copies of state laws, regulations, and guidance that the state believes demonstrate program adequacy.

(5) Copies of relevant state-tribal agreements if the state has negotiated with a tribe for the implementation of a permit program for non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste and/or MSWLFs on tribal lands.

The EPA Administrator has delegated the authority to make determinations of adequacy, as contained in the statute, to the EPA Regional Administrator. The appropriate EPA Regional Office, therefore, will use the information provided by each state to determine whether the state's permit program satisfies the statutory test reflected in the requirements of 40 CFR part 239. In all cases, the information will be analyzed to determine the adequacy of the state's permit program for ensuring compliance with the federal revised criteria.

Form numbers: None.

Respondents/affected entities: State, Local, or Tribal Governments.

Respondent's obligation to respond: Mandatory under section 4005(c) of RCRA.

Estimated number of respondents: 12.

Frequency of response: On occasion.

Total estimated burden: 968 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$41,674 (per year), which includes \$41,674 for annual labor and \$0 for annualized capital or operation & maintenance costs. All costs are labor costs, there are no capital/start-up or operation & maintenance costs associated with this ICR.

Changes in the estimates: The burden hours are likely to stay substantially the same.

Dated: November 13, 2025.

Andrew Baca,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2025–21341 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–12987–01–OLEM]

Forty-Eighth Update of the Federal Agency Hazardous Waste Compliance Docket

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Since 1988, the Environmental Protection Agency (EPA) has maintained a Federal Agency Hazardous Waste Compliance Docket (“Docket”) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). CERCLA requires EPA to establish a Docket that contains certain information reported to EPA by Federal facilities that manage hazardous waste or from which a reportable quantity of hazardous substances has been released. This document identifies the Federal facilities not previously listed on the Docket and identifies Federal facilities reported to EPA since the last update on April 21, 2025. In addition to the list of additions to the Docket, this document includes a section with revisions of the previous Docket list and a section of Federal facilities that are to be deleted from the Docket. Thus, the revisions in this update include two additions, zero deletions, and zero corrections to the Docket since the previous update.

DATES: This list is current as of October 3, 2025.

FOR FURTHER INFORMATION CONTACT:

Electronic versions of the Docket and more information on its implementation can be obtained at <https://www.epa.gov/fedfac/federal-agency-hazardous-waste-compliance-docket> by clicking on the link for *Cleanups at Federal Facilities* or by contacting Jonathan Tso, telephone number: (202) 564–0410; email address: tso.jonathan@epa.gov, Federal Agency Hazardous Waste Compliance Docket Coordinator, Office of Superfund and Emergency Management. Additional information on the Docket and a complete list of Docket sites can be obtained at: <https://www.epa.gov/fedfac/federal-agency-hazardous-waste-compliance-docket-1>.

SUPPLEMENTARY INFORMATION:

Table of Contents

- 1.0 Introduction
- 2.0 Regional Docket Coordinators
- 3.0 Revisions of the Previous Docket
- 4.0 Process for Compiling the Updated Docket
- 5.0 Facilities Not Included
- 6.0 Facility NPL Status Reporting, Including NFRAP Status
- 7.0 Information Contained on Docket Listing

1.0 Introduction

Section 120(c) of CERCLA, 42 U.S.C. 9620(c), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), requires EPA to establish the Federal Agency Hazardous Waste Compliance Docket. The Docket contains information on Federal facilities that manage hazardous waste and such information is submitted by Federal agencies to EPA under sections 3005, 3010, and 3016 of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6925, 6930, and 6937. Additionally, the Docket contains information on Federal facilities with a reportable quantity of hazardous substances that has been released and such information is submitted by Federal agencies to EPA under section 103 of CERCLA, 42 U.S.C. 9603. Specifically, RCRA section 3005 establishes a permitting system for certain hazardous waste treatment, storage, and disposal (TSD) facilities; RCRA section 3010 requires waste generators, transporters and TSD facilities to notify EPA of their hazardous waste activities; and RCRA section 3016 requires Federal agencies to submit biennially to EPA an inventory of their Federal hazardous waste facilities. CERCLA section 103(a) requires the owner or operator of a vessel or onshore or offshore facility to notify the National Response Center (NRC) of any spill or other release of a hazardous substance that equals or exceeds a reportable quantity (RQ), as defined by CERCLA section 101. Additionally, CERCLA section 103(c) requires facilities that have “stored, treated, or disposed of” hazardous wastes and where there is “known, suspected, or likely releases” of hazardous substances to report their activities to EPA.

CERCLA section 120(d) requires EPA to take steps to assure that a Preliminary Assessment (PA) be completed for those sites identified in the Docket and that the evaluation and listing of sites with a PA be completed within a reasonable time frame. The PA is designed to provide information for EPA to consider when evaluating the site for potential

response action or inclusion on the National Priorities List (NPL).

The Docket serves three major purposes: (1) to identify all Federal facilities that must be evaluated to determine whether they pose a threat to human health and the environment sufficient to warrant inclusion on the National Priorities List (NPL); (2) to compile and maintain the information submitted to EPA on such facilities under the provisions listed in section 120(c) of CERCLA; and (3) to provide a mechanism to make the information available to the public. Previous Docket updates are available at <https://www.epa.gov/fedfac/previous-federal-agency-hazardous-waste-compliance-docket-updates>.

This document provides some background information on the Docket. Additional information on the Docket requirements and implementation are found in the Docket Reference Manual, Federal Agency Hazardous Waste Compliance Docket found at <https://www.epa.gov/fedfac/docket-reference-manual-federal-agency-hazardous-waste-compliance-docket-interim-final> or obtained by calling the Regional Docket Coordinators listed below. This document also provides changes to the list of sites included on the Docket in three areas: (1) Additions, (2) Deletions, and (3) Corrections. Specifically, additions are newly identified Federal facilities that have been reported to EPA since the last update and now are included on the Docket; the deletions section lists Federal facilities that EPA is deleting from the Docket.¹ The information submitted to EPA on each Federal facility is maintained in the Docket repository located in the EPA Regional office of the Region in which the Federal facility is located; for a description of the information required under those provisions, see 53 FR 4280 (February 12, 1988). Each repository contains the documents submitted to EPA under the reporting provisions and correspondence relevant to the reporting provisions for each Federal facility.

In prior updates, information was also provided regarding No Further Remedial Action Planned (NFRAP) status changes. However, information on NFRAP and NPL status is no longer being provided separately in the Docket update as it is now available at: <https://www.epa.gov/fedfacts/federal-facility-cleanup-sites-searchable-list> or by contacting the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this document.

¹ See section 3.2 for the criteria for being deleted from the Docket.

2.0 Regional Docket Coordinators

Contact the following Docket Coordinators for information on Regional Docket repositories:

- *US EPA Region 1.* Mya Winslow (HBS), 5 Post Office Square, Suite 100, Mail Code: 01–5, Boston MA 02109–3912, (617) 918–1594.
- *US EPA Region 2.* James Desir, 290 Broadway, New York, NY 10007–1866, (212) 637–4342.
- *US EPA Region 3.* Connor O’Loughlin (3HS12), 1650 Arch Street, Philadelphia, PA 19107, (215) 814–3304.
- *US EPA Region 4.* Emily Jones (9T25), 61 Forsyth St., SW, Atlanta, GA 30303, (404) 562–8334.
- *US EPA Region 5.* David Brauner (SR–6J), 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886–1526.
- *US EPA Region 6.* Philip Ofosu (6SF–RA), 1445 Ross Avenue, Dallas, TX 75202–2733, (214) 665–3178.
- *US EPA Region 7.* Matthew Smith (SUPRERSB), 11201 Renner Blvd., Lenexa, KS 66219, (913) 551–7527.
- *US EPA Region 8.* Ryan Dunham (EPR–F), 1595 Wynkoop Street, Denver, CO 80202, (303) 312–6627.
- *US EPA Region 9.* Ashley Mrzljak (SFD–6–1), 600 Wilshire Boulevard, Suite 940, Los Angeles, CA 90017, (213) 244–1839.
- *US EPA Region 10.* Jeffree Fetters, 1200 Sixth Avenue, Seattle, WA 98101, (206) 553–1583.

3.0 Revisions of the Previous Docket

This section includes a discussion of the additions, deletions and corrections to the list of Docket facilities since the previous Docket update.

3.1 Additions

These Federal facilities are being added primarily because of new information obtained by EPA (for example, recent reporting of a facility pursuant to RCRA sections 3005, 3010, or 3016 or CERCLA section 103). CERCLA section 120, as amended by the Defense Authorization Act of 1997, specifies that EPA take steps to assure that a Preliminary Assessment (PA) be completed within a reasonable time frame for those Federal facilities that are included on the Docket. Among other things, the PA is designed to provide information for EPA to consider when evaluating the site for potential response action or listing on the NPL. This document includes two additions.

3.2 Deletions

There are no statutory or regulatory provisions that address deletion of a facility from the Docket. However, if a facility is incorrectly included on the

Docket, it may be deleted from the Docket. The criteria EPA uses in deleting sites from the Docket include: a facility for which there was an incorrect report submitted for hazardous waste activity under RCRA (e.g., 40 CFR 262.44); a facility that was not Federally-owned or operated at the time of the listing; a facility included more than once (i.e., redundant listings); or when multiple facilities are combined under one listing. (See Docket Codes (*Reasons for Deletion of Facilities*)) for a more refined list of the criteria EPA uses for deleting sites from the Docket.) Facilities being deleted no longer will be subject to the requirements of CERCLA section 120(d). This document includes zero deletions.

3.3 Corrections

Changes necessary to correct the previous Docket are identified by both EPA and Federal agencies. The corrections section may include changes in addresses or spelling, and corrections of the recorded name and ownership of a Federal facility. In addition, changes in the names of Federal facilities may be made to establish consistency in the Docket or between the Superfund Enterprise Management System (SEMS) and the Docket. For the Federal facility for which a correction is entered, the original entry is as it appeared in previous Docket updates. The corrected update is shown directly below, for easy comparison. This document includes zero corrections.

4.0 Process for Compiling the Updated Docket

In compiling the newly reported Federal facilities for the update being published in this document, EPA extracted the names, addresses, and identification numbers of facilities from four EPA databases—the WebEOC, the Biennial Inventory of Federal Agency Hazardous Waste Activities, the Resource Conservation and Recovery Act Information System (RCRAInfo), and SEMS—that contain information about Federal facilities submitted under the four provisions listed in CERCLA section 120(c).

EPA assures the quality of the information on the Docket by conducting extensive evaluation of the current Docket list and contacts the other Federal Agency (OFA) with the information obtained from the databases identified above to determine which Federal facilities were, in fact, newly reported and qualified for inclusion on the update. EPA is also striving to correct errors for Federal facilities that were previously reported. For example, state-owned or privately-owned

facilities that are not operated by the Federal government may have been included. Such problems are sometimes caused by procedures historically used to report and track Federal facilities data. Representatives of Federal agencies are asked to contact the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this document if revisions of this update information are necessary.

5.0 Facilities Not Included

Certain categories of facilities may not be included on the Docket, such as: (1) Federal facilities formerly owned by a Federal agency that at the time of consideration was not Federally-owned or operated; (2) Federal facilities that are small quantity generators (SQGs) that have not, more than once per calendar year, generated more than 1,000 kg of hazardous waste in any single month; (3) Federal facilities that are very small quantity generators (VSQGs) that have never generated more than 100 kg of hazardous waste in any month; (4) Federal facilities that are solely hazardous waste transportation facilities, as reported under RCRA section 3010; and (5) Federal facilities that have mixed mine or mill site ownership.

An EPA policy issued in June 2003 provided guidance for a site-by-site evaluation as to whether “mixed ownership” mine or mill sites, typically created as a result of activities conducted pursuant to the General Mining Law of 1872 and never reported under section 103(a) of CERCLA, should be included on the Docket. For purposes of that policy, mixed ownership mine or mill sites are those located partially on private land and partially on public land. This policy is found at <https://www.epa.gov/fedfac/policy-listing-mixed-ownership-mine-or-mill-sites-created-result-general-mining-law-1872>. The policy of not including these facilities may change; facilities now omitted may be added at some point if EPA determines that they should be included.

6.0 Facility NPL Status Reporting, Including NFRAP Status

EPA tracks the NPL status of Federal facilities listed on the Docket. An updated list of the NPL status of all Docket facilities, as well as their NFRAP status, is available at <https://www.epa.gov/fedfacts/federal-facility-cleanup-sites-searchable-list> or by contacting the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this document. In prior

updates, information regarding NFRAP status changes was provided separately.

7.0 Information Contained on Docket Listing

The information is provided in three tables. The first table is a list of additional Federal facilities that are being added to the Docket. The second table is a list of Federal facilities that are being deleted from the Docket. The third table is for corrections.

The Federal facilities listed in each table are organized by the date reported. Under each heading is listed the name and address of the facility, the Federal agency responsible for the facility, the statutory provision(s) under which the facility was reported to EPA, and a code.²

The statutory provisions under which a Federal facility is reported are listed in a column titled "Reporting Mechanism." Applicable mechanisms are listed for each Federal facility: for example, sections 3005, 3010, 3016 of RCRA, 103(c) of CERCLA, or Other. "Other" has been added as a reporting mechanism to indicate those Federal facilities that otherwise have been identified to have releases or threat of releases of hazardous substances. The National Contingency Plan at 40 CFR 300.405 addresses discovery or notification, outlines what constitutes discovery of a hazardous substance release, and states that a release may be discovered in several ways, including: (1) a report submitted in accordance with section 103(a) of CERCLA, *i.e.*, reportable quantities codified at 40 CFR part 302; (2) a report submitted to EPA in accordance with section 103(c) of CERCLA; (3) investigation by government authorities conducted in accordance with section 104(e) of

CERCLA or other statutory authority; (4) notification of a release by a Federal or state permit holder when required by its permit; (5) inventory or survey efforts or random or incidental observation reported by government agencies or the public; (6) submission of a citizen petition to EPA or the appropriate Federal facility requesting a preliminary assessment, in accordance with section 105(d) of CERCLA; (7) a report submitted in accordance with section 311(b)(5) of the Clean Water Act; and (8) other sources. As a policy matter, EPA generally believes it is appropriate for Federal facilities identified through the CERCLA discovery and notification process to be included on the Docket.

The complete list of Federal facilities that now make up the Docket and the NPL and NFRAP status are available to interested parties and can be obtained at <https://www.epa.gov/fedfacts/federal-facility-cleanup-sites-searchable-list> or by contacting the EPA HQ Docket Coordinator at the address provided in the **FOR FURTHER INFORMATION CONTACT** section of this document. As of the date of this document, the total number of Federal facilities that appear on the Docket is 2,399.

7.1 Docket Codes/Reasons for Deletion of Facilities

- *Code 1.* Small-Quantity Generator and Very Small Quantity Generator. Show citation box.
- *Code 2.* Never Federally Owned and/or Operated.
- *Code 3.* Formerly Federally Owned and/or Operated but not at time of listing.
- *Code 4.* No Hazardous Waste Generated.
- *Code 5.* This code is no longer used.
- *Code 6.* Redundant Listing/Site on Facility.

- *Code 7.* Combining Sites Into One Facility/Entries Combined.
- *Code 8.* Does Not Fit Facility Definition.

7.2 Docket Codes/Reasons for Addition of Facilities

- *Code 15.* Small-Quantity Generator with either a RCRA 3016 or CERCLA 103 Reporting Mechanism.
- *Code 16.* One Entry Being Split Into Two (or more)/Federal Agency Responsibility Being Split.
- *Code 16A.* NPL site that is part of a facility already listed on the Docket.
- *Code 17.* New Information Obtained Showing That Facility Should Be Included.
- *Code 18.* Facility Was a Site on a Facility That Was Disbanded; Now a Separate Facility.
- *Code 19.* Sites Were Combined Into One Facility.
- *Code 19A.* New Currently Federally Owned and/or Operated Facility Site.

7.3 Docket Codes/Types of Corrections of Information About Facilities

- *Code 20.* Reporting Provisions Change.
- *Code 20A.* Typo Correction/Name Change/Address Change.
- *Code 21.* Changing Responsible Federal Agency. (If applicable, new responsible Federal agency submits proof of previously performed PA, which is subject to approval by EPA.)
- *Code 22.* Changing Responsible Federal Agency and Facility Name. (If applicable, new responsible Federal Agency submits proof of previously performed PA, which is subject to approval by EPA.)
- *Code 24.* Reporting Mechanism Determined To Be Not Applicable After Review of Regional Files.

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #48—ADDITIONS

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code	Date
Pacific Northwest National Laboratory Sequim Campus.	1529 West Sequim Bay Road.	Sequim	WA	98382	Energy	RCRA 3010	17	Update #48
US DOC NOAA NW Fisheries Science Center.	2725 Montlake Boulevard East.	Seattle	WA	98112	Commerce	RCRA 3010	17	Update #48

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #48—DELETIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code	Date

² Each Federal facility listed in the update has been assigned a code that indicates a specific reason

for the addition or deletion. The code precedes this list.

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #48—CORRECTIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code	Date

Mark Barolo,

Director, Office of Superfund and Emergency Management, Office of Land and Emergency Management.

[FR Doc. 2025–21345 Filed 11–26–25; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: EIB–2026–001]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of \$100 Million: AP774431XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with the Export-Import Bank Act of 1945, as amended, the Export-Import Bank of the United States (“EXIM”) has received an application for final commitment for a long-term loan or financial guarantee in excess of \$100 million. Comments received within the comment period specified below will be presented to the EXIM Board of Directors prior to final action on this Transaction.

DATES: Comments must be received on or before December 23, 2025 to be assured of consideration before final consideration of the transaction by the Board of Directors of EXIM.

ADDRESSES: Comments may be submitted through [Regulations.gov](https://www.regulations.gov) at www.regulations.gov. To submit a comment, enter EIB–2026–001 under the heading “Enter Keyword or ID” and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2026–001 on any attached document.

SUPPLEMENTARY INFORMATION:

Reference: AP774431XX.

Purpose and Use:

Brief description of the purpose of the transaction: To support the procurement of satellite component manufacturing equipment, production facility, and interior modifications.

Brief non-proprietary description of the anticipated use of the items being exported: The supported goods will be used to produce satellite components.

To the extent that EXIM is reasonably aware, the item(s) being exported are

not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Supplier: Various Suppliers.

Obligor: CesiumAstro Inc.

Guarantor(s): All subsidiaries.

Description of Items Being Exported: Components.

Information on Decision: Information on the final decision for this transaction will be available in the “Board Agenda and Meeting Minutes” on <https://www.exim.gov/news/meeting-minutes>.

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Authority: Section 3(c)(10) of the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635a(c)(10)).

Deidre Hodge,

Assistant Corporate Secretary.

[FR Doc. 2025–21385 Filed 11–26–25; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CG Docket Nos. 17–59, 02–278, 25–307, WC Docket No. 17–97; FCC 25–76; FR ID 319340]

Federal Communications Commission Announces Intent To Dismiss Certain Older Petitions and Applications Related to the Telephone Consumer Protection Act

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: In this document, the Federal Communications Commission (FCC or Commission) announces the availability of the FCC’s Public Notice stating the intent to dismiss with prejudice certain older Petitions for Reconsideration and Applications for Review related to the Telephone Consumer Protection Act.

DATES: Objections to dismissal of its Petition for Reconsideration or

Application for Review are due on or before January 12, 2026.

FOR FURTHER INFORMATION CONTACT: John B. Adams, Consumer Policy Division, Consumer and Governmental Affairs Bureau at (202) 418–2854 or JohnB.Adams@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s Ninth Further Notice of Proposed Rulemaking; Seventh Further Notice of Proposed Rulemaking; Further Notice of Proposed Rulemaking; and Public Notice (*Public Notice*) in CG Docket No. 17–59, WC Docket No. 17–97, CG Docket Nos. 02–278 and 25–307; FCC 25–76, released on October 29, 2025. The full text of this document, including instructions on how to file objection letters; the table listing the Petitions for Reconsideration and Applications for Review intended to be dismissed with prejudice; and copies of any subsequently filed documents in this matter, will be available for public inspection and copying via ECFS at: <https://www.fcc.gov/ecfs/> and available online at <https://docs.fcc.gov/public/attachments/FCC-25-76A1.pdf>.

To request this document in accessible formats for people with disabilities (Braille, large print, electronic files, audio format) or to request reasonable accommodations (e.g. accessible format documents, sign language interpreters, CART), send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice).

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2025–21323 Filed 11–26–25; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1081; FR ID 318966]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as

required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before January 27, 2026. 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: 3060-1081.

Title: Sections 1.2002, 54.201, 54.202, 54.205, Telecommunications Carriers Eligible for Universal Service Support.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 24 respondents; 28 responses.

Estimated Time per Response: 1-40 hours.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority is contained in sections 201(b), 214(e)(6), and 303(r) of the

Communications Act of 1934, as amended, 47 U.S.C. 201(b), 214(e)(6), 303(r).

Frequency of Response: One-time reporting requirement.

Total Annual Burden: 808 hours.

Total Annual Cost: No cost.

Needs and Uses: Section 254(e) of the Communications Act of 1934, as amended (Act) provides that "only an ETC designated under section 214(e) shall be eligible to receive specific Federal universal service support."

Section 214(e)(2) of the Act gives state commissions the primary responsibility for performing ETC designations.

Section 214(e)(6) vests the Commission with authority to designate as an ETC "a common carrier providing telephone exchange service and exchange access that is not subject to the jurisdiction of a State commission."

Section 214(e)(4) provides that state commissions, in a case of a common carrier designated under paragraph (2) of this section, or the Commission, in a case of a common carrier designated under paragraph (6) of this section, "shall permit" an ETC to relinquish its designation "in any area served by more than one" ETC so long as "the remaining [ETCs] ensure that all customers served by the relinquishing carrier will continue to be served," and the relinquishing carrier provides "sufficient notice to permit the purchase or construction of adequate facilities by any remaining eligible telecommunications carrier." The ETC must provide advance notice to the state commission or the Commission.

The Commission's rules for ETC designation require the collection of information specified below, except where the Commission has waived information collection requirements when enforcing them would not serve the public interest.

On October 20, 2023, the Commission adopted the *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*). In the *Administrative Order*, the Commission modified, in relevant part, section 205 of the Commission's rules, to require an ETC that intends to relinquish its ETC designation to provide: (1) advance notice to the state commission and to the Commission of such intention to relinquish, and (2) notice to the Commission of the state authority's decision to permit or deny such relinquishment, within 10 days of its decision. These filings must be submitted regardless of whether the ETC is currently receiving federal support. The Commission identified its statutory

authority to impose these requirements through section 254 of the Act and as reasonably ancillary thereto.

The Commission notes that information collections associated with the Lifeline-only ETC designations and relinquishments are reflected in OMB Control No. 3060-0819.

This information collection addresses the burdens associated with these requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2025-21326 Filed 11-26-25; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0853; FR ID 319353]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees. The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before December 29, 2025.

ADDRESSES: Comments should be sent to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Your comment must be submitted into www.reginfo.gov per the

above instructions for it to be considered. In addition to submitting in www.reginfo.gov also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to PRA@fcc.gov and to Nicole.Ongele@fcc.gov. Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418-2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

OMB Control Number: 3060-0853.

Title: Certification by Administrative Authority to Billed Entity Compliance with the Children's internet Protection Act Form, FCC Form 479; Receipt of

Service Confirmation and Certification of Compliance with the Children's internet Protection Act Form, FCC Form 486; and Funding Commitment and Adjustment Request Form, FCC Form 500.

Form Numbers: FCC Forms 479, 486 and 500.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents and Responses: 84,010 respondents, 94,203 responses.

Estimated Time per Response: 1 hour for FCC Form 479, 1 hour for FCC Form 486, 1 hour for FCC Form 500, 0.75 hours for maintaining and updating the internet Safety Policy, and 0.5 hours for recordkeeping requirements.

Frequency of Response: On occasion and 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(i), 155, 201, 205, 214, 219, 220, 254, 303(r), 403, and 1302.

Total Annual Burden: 78,319 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB), which is an extension of a currently approved collection, to obtain a full three-year clearance from OMB. The requirements contained herein are necessary to implement the Congressional mandate for universal service. It provides the Commission and USAC with the necessary information to administer the E-Rate program, determine the amount of support entities seeking funding are eligible to receive, to determine if entities are complying with the Commission's rules, and to prevent waste, fraud, and abuse. The information will also allow the Commission to evaluate the extent to which the E-Rate program is meeting the statutory objectives specified in section 254 of the 1996 Act, the Commission's performance goals established in the *2014 First and Second E-Rate Orders*, and to evaluate the need and feasibility for any future revisions to program rules.

FCC Form 486 was revised. On July 29, 2024 the Commission released a Report and Order and Further Notice of Proposed Rulemaking (WC Docket No. 21-31, FCC 24-76) (*2024 Wi-Fi Hotspots Order*); finding that the off-premises use of wireless internet services and the Wi-Fi hotspot devices needed to deliver the services; serves an educational purpose

and are eligible for E-Rate support. The *2024 Wi-Fi Hotspots Order*, 89 FR 67303, August 20, 2024, would have added the following certifications to the FCC Form 486: applicants that receive support for Wi-Fi hotspots and service for off-premises use uses the FCC Form 486 to certify that they have updated and publicly posted their "acceptable use policy (AUP)" consistent with the requirements in 47 CFR 54.516(f); the Wi-Fi hotspots and/or services the school, library, or consortium purchased using E-Rate support for off-premises use have been activated and made available to students, school staff, and/or library patrons; public notice of their availability has been provided; and the authorized person is not requesting reimbursement for Wi-Fi hotspots and/or services that have not been made available for distribution. On September 30, 2025, the Commission adopted the *Hotspots Order on Reconsideration* (WC Docket No. 21-31, FCC 25-62) (*Hotspots Order on Reconsideration*), that rescinds the *2024 Wi-Fi Hotspots Order*, and removes the eligibility of E-Rate support for off-premises use of wireless mobile internet services and the Wi-Fi hotspot devices needed to deliver the services. The Wi-Fi hotspots and service-related rules, including the certifications, are no longer applicable and are removed from this information collection.

The hourly burden will increase by 10,044 hours for FCC Forms 479, 486, and 500. The public burden for the collection contained herein will increase to 78,319 burden hours.

FCC Form 486 "Receipt of Service Confirmation and Certification of Compliance with the Children's internet Protection Act." After the Administrator reviews the funding request and commits to fund the eligible equipment and/or services requested, applicants use the FCC Form 486 to notify USAC of their service start dates for their funding requests. Universal service support will not be paid on an approved funding commitment prior to receipt of the FCC Form 486.

Billed entities also use the FCC Form 486 to certify compliance with the Children's internet Protection Act (CIPA), see 47 U.S.C. 254 (h)-(l), or qualification for a CIPA exemption when they seek discounts for category one services (*i.e.*, internet access) and category two services (*i.e.*, internal connections, managed internal broadband services, or basic maintenance of internal connections). When the billed entities are members of a larger consortia, they individually certify CIPA compliance by submitting the FCC Form 479 "Certification by Administrative Authority to Billed

Entity of Compliance with Children's internet Protection Act" to the consortium leader. The consortium leader can then file the FCC Form 486 certifying CIPA compliance on behalf of the consortia. CIPA requires schools and libraries that have computers with internet access to certify that they have in place certain internet safety policies and technology protection measures to be eligible to receive program services under section 254(h) of the Act. *See also* 47 CFR 54.520. The FCC Form 486 is also a necessary prerequisite for invoicing and payment.

FCC Form 500 "Funding Commitment Adjustment Request." The FCC Form 500 is used by E-Rate participants to make adjustments to previously filed forms, such as changing the contract expiration date noted on the FCC Form 471, changing the funding year service start date listed on the FCC Form 486, cancelling or reducing the amount of a funding request, and extending the service delivery deadline for non-recurring services.

All of the requirements contained in this information collection are necessary to implement the Congressional mandate for the E-Rate program and reimbursement process.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2025-21316 Filed 11-26-25; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[MB Docket No. 25-322; DA 25-961; FR ID 319167]

Empowering Local Broadcast TV Stations To Meet Their Public Interest Obligations: Exploring Market Dynamics Between National Programmers and Their Affiliates

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: In this document, the Media Bureau seeks comment on the current market, regulatory, and contractual dynamics governing the relationship between local television broadcast stations and national programmers in order to identify any barriers that may be preventing local broadcast television stations from meeting their public interest obligations and responding to the needs of their local communities.

DATES: Comments are due by December 10, 2025. Reply Comments are due by December 24, 2025.

ADDRESSES: You may submit comments, identified by MB Docket No. 25-322, electronically or on paper. See

SUPPLEMENTARY INFORMATION for specific information and addresses for electronic or paper filings.

FOR FURTHER INFORMATION CONTACT:

Kathy Berthot, Federal Communications Commission, Media Bureau, Policy Division, *Kathy.Berthot@fcc.gov*, (202) 418-7454.

SUPPLEMENTARY INFORMATION: This is a summary of the Media Bureau's Public Notice, *Empowering Local Broadcast TV Stations to Meet Their Public Interest Obligations: Exploring Market Dynamics Between National Programmers and Their Affiliates*, MB Docket No. 25-322, DA 25-961, released on November 19, 2025. The full text of this document is available for public inspection and can be downloaded at <https://docs.fcc.gov/public/attachments/DA-25-961A1.pdf>. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format) by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

Comment Period and Filing Procedures. Interested parties may file comments on or before the dates provided in the **DATES** section of this document. Comments must be filed in MB Docket No. 25-322. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

- All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: <https://www.fcc.gov/ecfs/>.

- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

Procedural Matters

Ex Parte Rules. The proceeding this Public Notice initiates shall be treated as an "exempt" proceeding in accordance with the Commission's *ex parte* rules. *Ex parte* presentations are permissible and need not be publicly disclosed, but may be if the presenter chooses.

Synopsis

Congress has provided the FCC with broad and expansive authority over the provision of broadcast television service. Specifically, television broadcasters are required by both the Communications Act and the terms of their FCC-issued licenses to operate in the public interest. Television broadcasters have this public interest obligation because the government has given them the privilege of using a scarce national resource—the public airwaves—and in doing so has necessarily excluded others that might want to broadcast their own programming over that spectrum. This public interest obligation distinguishes television broadcasters from other types of program distributors, including cable companies, streaming services, podcasts, and more, that were never given free access to the public airwaves or a federal license to broadcast on that spectrum.

By this Public Notice, the Media Bureau continues its efforts to empower local television broadcasters to meet their public interest obligations. Consistent with longstanding FCC precedent and rules, we want to identify any barriers that may be preventing local broadcast television stations from meeting their public interest obligations and responding to the needs of their local communities. In doing so, we will focus here on seeking comment on the current market, regulatory, and contractual dynamics governing the relationship between local television broadcast stations on the one hand and national programmers on the other.

The obligation to operate a broadcast television station in the public interest is fundamental to holding Commission licenses. This obligation predates the Commission and the Communications Act of 1934, having been codified in the Radio Act of 1927. Consistent with the First Amendment, the Commission has afforded licensees leeway in meeting this obligation. But courts have long held that the First Amendment does not relieve a licensee of its public interest obligation, nor does it absolve the Commission of its statutory duty to ensure those licensees meet public interest requirements.

Much of the programming that viewers associate with TV programming is in fact provided by a national network programmer through a local broadcast TV station that affiliates with the national programmer. In these arrangements, the local broadcast TV affiliate station is the actual holder of the broadcast license. As the holder of a broadcast license, it is incumbent upon the licensee—not the network—to ensure that it is meeting its public interest obligation by providing programming that serves the needs of the communities it serves. Nonetheless, the FCC has been clear over the years that the relationships between local television stations and the national programmers are relevant to the FCC's enforcement of the public interest standard.

Despite the importance of the network/affiliate relationship to broadcasters' fulfillment of their public interest obligations, the FCC has not undertaken a review of the complex issues raised by that relationship in more than 15 years. Stakeholders representing the interests of affiliated or local television broadcasters have suggested that, in this time, an imbalance has developed in this relationship—that the horizontally and vertically integrated companies that now own national programming networks, cable companies, and streaming platforms can overpower affiliated broadcast television stations. This imbalance, in their view, frustrates local broadcasters in their efforts to fulfill their public interest obligations. Although the FCC does not directly regulate the national programmers as such, the Supreme Court has held that the relationship between networks and affiliates is well within the Commission's regulatory jurisdiction. Indeed, the FCC has long had rules on its book that regulate the rights that national programmers can obtain from local television broadcasters.

This Public Notice is an important step in gathering the information needed to consider whether the national programming networks are exerting undue influence or control over their affiliate stations, whether the Commission's rules are operating to ensure the independence of affiliate stations, and whether the Commission's rules require any clarification or amendment to ensure that local affiliates are empowered to meet their statutory public interest obligations.

Changes in the network/affiliate relationship. We seek comment on the status of the relationship between the national programmers and affiliated local broadcast TV stations and how

their relative bargaining positions may have changed in recent years. How have changes in the broadcast industry, such as consolidation of station ownership and the introduction of NextGen TV, affected the relative bargaining positions of networks and their affiliates? How have changes in the broader market for video programming, including the rapid growth of streaming services and cord-cutting by consumers, impacted these relative bargaining positions? Do these impacts differ for or among Big Four (i.e., ABC, CBS, NBC, and Fox) network affiliates and non-Big Four network affiliates? We also seek comment on the relative bargaining positions of large station group owners as compared to smaller station group owners and single stations in negotiating affiliation agreements with networks today. Are smaller station group owners and single stations typically subject to more onerous and restrictive terms in their affiliation agreements with networks?

Licensee control over station programming and operations. Under the Communications Act and the Commission's rules, affiliates, as the licensees of local television stations, must retain ultimate control over programming, operations, and other critical decisions with respect to their stations, and network affiliations must not undermine this control. We seek comment on whether and how network affiliation agreements or the current dynamics of the network/affiliate relationship may be impeding the ability of affiliates to maintain ultimate control over the critical decisions of their stations, including station programming and operations.

We seek comment on whether such control is attributable to restrictive conditions in affiliation agreements or a result of an imbalance of power between the networks and their affiliates or other factors. Are there other network practices today that hinder the ability of their affiliate stations to maintain control over programming decisions? For example, many local affiliates object to provisions that limit their ability to negotiate directly with certain video programming distributors. Should the Commission amend or clarify its rules to address any such situations and, if so, how? What other steps can the Commission take to help ensure that network practices do not undermine the ability of stations to maintain ultimate control over their programming and operations?

Commission rules governing affiliation agreements. We seek comment on how networks are currently handling their relationships with affiliates with regard to the specific

program practices governed by Section 73.658 of the Commission's rules, 47 CFR 73.658. Section 73.658 includes the exclusive affiliation rule; the territorial exclusivity rule; the option-time rule; the right to reject rule; and the dual network rule. Are the requirements of the Commission's rules generally observed or are there general or specific instances where network agreements violate the requirements or undermine the purpose and intent of the requirements? Commenters are encouraged to provide specific examples. What impact does such conduct have on the ability of local stations to serve the needs and interests of their communities? Have market conditions changed in the time since these rules were adopted in a manner that necessitates further Commission guidance on or clarification of these requirements? What other actions can the Commission take to ensure compliance with these requirements?

Consistent with the FCC's right to reject rule, we seek comment in particular regarding the preemption of national programming by local broadcast TV stations. As indicated in that rule, the FCC has determined that affiliation agreements should not include provisions that limit right-to-reject preemptions for "greater local or national importance" to breaking news events or any other specific type of programming; prevent affiliates from rejecting a program as "unsatisfactory or unsuitable or contrary to the public interest" because they have carried a similar network program in the past; or impose monetary or nonmonetary penalties on affiliates based on preemptions protected by the right-to-reject rule. Should the FCC consider any changes to this rule? Are national programmers able to take actions or threaten to punish local broadcast TV stations that attempt to exercise their lawful right to preempt national programming?

Networks' undue influence over affiliation agreements. We also seek input on the extent to which networks use their positions in the market to unduly influence the terms of the affiliation agreements with their affiliate stations. For instance, the national programming networks have moved some popular programming from broadcast television to their streaming platforms, and sometimes simulcast marquee network sports programming, such as the Super Bowl and the Olympics, on their streaming platforms. Does a network's growing focus on their streaming platforms suggest that the networks hold considerable leverage today in their contract negotiations with

their affiliates? We seek comment on the extent to which networks may be using leverage to impose burdensome and restrictive terms in the affiliation agreements with their local affiliate stations. How have such terms impacted the ability of affiliate stations to operate as trusted sources of local news and other local programming and carry out other essential operational functions? Are there actions that the Commission could take to help restore the balance in the network/affiliate relationship and ensure that networks are not exercising undue influence over the terms of affiliation agreements?

Good faith negotiations between networks and their affiliates. Broadcast television stations and multichannel video programming distributors (MVPDs) are required under the Communications Act and the Commission's rules to negotiate retransmission consent in good faith. The focus of the good faith bargaining rules is not on the substantive terms of retransmission consent negotiations but rather is to ensure that the parties "meet to negotiate retransmission consent and that such negotiations are conducted in an atmosphere of honesty, purpose, and clarity of process." We seek comment on whether the network/affiliate negotiation process would benefit from adoption of similar good faith bargaining rules. We also seek comment on what authority, if any, the Commission has to adopt good faith bargaining rules for networks and their affiliate stations.

Future Rulemaking. If the Commission were to consider initiating a broader proceeding, what other policy alternatives might foster competition in affiliate negotiations? In 1941, for instance, the Commission issued its Chain Broadcasting Report, which was designed to address inequities between radio networks and their affiliated stations. In the early 1940s, radio broadcasting in the United States was almost exclusively provided by four national AM radio networks, similar to today's television broadcast market, which is dominated by the four large networks that are now horizontally integrated, owning multiple service platforms and stations, including cable, broadcasting, and streaming services. In the Chain Broadcasting Report, the Commission found that certain regulations were necessary to address unfair practices in negotiations between the radio networks and local affiliate stations. For example, the report stated that affiliates should be allowed to broadcast programs of other networks as well as to schedule their own programs. Should the Commission consider

adopting regulations similar to these in light of the changes in the broadcast market that have led to anticompetitive leverage and behavior by large networks?

Remedial Actions. If the FCC subsequently determines that certain contract provisions and related network practices should be prohibited by rule, we seek comment on how to address offending affiliate agreements in order to restore full control of the license to the affiliate. For example, should the Commission simply declare that such provisions are unenforceable and/or provide a safe harbor for affiliates and networks to renegotiate their agreements within a specified period of time not to exceed the next renewal filing period for television stations? Moving forward, should the Commission engage in a more detailed review of affiliate agreements when reviewing license renewals in order to detect and address discriminatory or anticompetitive terms? We seek comment on these and other remedial provisions as possible avenues for the Commission to explore in addressing these marketplace issues.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2025-21318 Filed 11-26-25; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings: Notice of Meeting Held With Less Than Seven Days Advance Notice

TIME AND DATE: 10:20 a.m. on Tuesday, November 25, 2025.

PLACE: The meeting was held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The Board of Directors of the Federal Deposit Insurance Corporation met to consider matters related to the Corporation's resolution, supervision, and corporate activities. In calling the meeting, the Board determined by majority vote, on motion of Acting Chairman Travis Hill, seconded by Director Jonathan V. Gould (Comptroller of the Currency), that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation;

and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A), and (c)(9)(B)).

CONTACT PERSON FOR MORE INFORMATION:

For further information, please contact Debra A. Decker, Executive Secretary, FDIC, at FDICBoardMatters@fdic.gov.

Dated this the 25th day of November, 2025.

Federal Deposit Insurance Corporation.

Debra A. Decker,

Executive Secretary.

[FR Doc. 2025-21507 Filed 11-25-25; 4:15 pm]

BILLING CODE 6714-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Designated Reserve Ratio for 2026

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Notice of Designated Reserve Ratio for 2026.

SUMMARY: Pursuant to the Federal Deposit Insurance Act (FDI Act), the Board of Directors (Board) of the Federal Deposit Insurance Corporation (FDIC) designates that the Designated Reserve Ratio (DRR) for the Deposit Insurance Fund shall remain at 2 percent for 2026. The Board is publishing this notice as required by the FDI Act.

FOR FURTHER INFORMATION CONTACT:

Ashley Mihalik, Deputy Director, Deposit Insurance and Risk Analysis, Division of Insurance and Research, 202-898-3793, amihalik@fdic.gov; Daniel Hoople, Acting Associate Director, Financial Risk Management Branch, Division of Insurance and Research, 202-898-3835, dhoople@fdic.gov; or Ryan McCarthy, Counsel, Legal Division, 202-898-7301, rymccarthy@fdic.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the FDI Act, the Board designates that the DRR for the Deposit Insurance Fund shall remain at 2 percent for 2026. The Board is publishing this notice as required by section 7(b)(3)(A)(i) of the FDI Act (12 U.S.C. 1817(b)(3)(A)(i)). There is no need to amend 12 CFR 327.4(g), the section of the FDIC's regulations that sets forth the DRR, because the DRR for 2026 is the same as the current DRR.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC November 25, 2025.

Jennifer M. Jones,

Deputy Executive Secretary.

[FR Doc. 2025–21460 Filed 11–26–25; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings: Notice of Meeting Held With Less Than Seven Days Advance Notice

TIME AND DATE: 10:00 a.m. on November 25, 2025.

PLACE: The meeting was held in the FDIC Board Room, 550 17th Street NW, Washington, DC, and was webcast to the public.

STATUS: Open to public observation via webcast.

MATTERS TO BE CONSIDERED: Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is given that the Federal Deposit Insurance Corporation’s Board of Directors met in open session to consider the following matters:

Summary Agenda

Final Rule: Adjusting and Indexing Certain Regulatory Thresholds.

Designated Reserve Ratio for 2026.

Final Rule; Delay of Compliance Date: FDIC Official Signs and Advertising Requirements, False Advertising, Misrepresentation of Insured Status, and Misuse of the FDIC’s Name or Logo.

Minutes of a Board of Directors’ Meeting Previously Distributed.

Discussion Agenda

Notice of Proposed Rulemaking: Regulatory Capital Rule: Revisions to the Community Bank Leverage Ratio Framework.

Final Rule: Regulatory Capital Rule: Modifications to the Enhanced Supplementary Leverage Ratio Standards for U.S. Global Systemically Important Bank Holding Companies and Their Subsidiary Depository Institutions; Total Loss-Absorbing Capacity and Long-Term Debt Requirements for U.S. Global Systemically Important Bank Holding Companies.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Debra A. Decker, Executive Secretary, FDIC, at FDICBoardMatters@fdic.gov.

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

Dated at Washington, DC, on November 25, 2025.

Federal Deposit Insurance Corporation.

Debra A. Decker,

Executive Secretary.

[FR Doc. 2025–21508 Filed 11–25–25; 4:15 pm]

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, Benjamin W. McDonough, Deputy Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 15, 2025.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to

Comments.applications@phil.frb.org:

1. *Kenneth R. Lehman, Fort Lauderdale, Florida*; to acquire voting shares of Sabine Bancshares, Inc., and thereby indirectly acquire voting shares

of Sabine State Bank and Trust Company, both of Many, Louisiana.

B. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to

Comments.applications@stls.frb.org:

1. *Bedford Holdings, LLP, Emily Nadeau and Jason Nadeau*, as co-managing general partners, all of Little Rock, Arkansas; to join the Eldridge Family Control Group, a group acting in concert, to acquire voting shares of Oak Tree Financial Corporation, Inc., Rogers, Arkansas, and thereby indirectly acquire voting shares of Riverside Bank, Sparkman, Arkansas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–21473 Filed 11–26–25; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board’s Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying

information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than December 24, 2025.

A. *Federal Reserve Bank of Dallas* (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201-2272. Comments can also be sent electronically to Comments.applications@dal.frb.org:

1. *Third Coast Bancshares, Inc.*, Houston, Texas; to acquire Keystone Bancshares, Inc., and thereby indirectly acquire Keystone Bank, SSB, both of Bee Cave, Texas.

2. *CSBL Acquisition, Inc.*, San Antonio, Texas; to become a bank holding company by acquiring Luling Bancshares, Inc., and thereby indirectly acquiring Citizens State Bank of Luling, both of Luling, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025-21569 Filed 11-26-25; 8:45 am]

BILLING CODE 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, Benjami W. McDonough, Deputy Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than December 9, 2025.

A. *Federal Reserve Bank of Kansas City* (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001. Comments can also be sent electronically to KCApplicationComments@kc.frb.org:

1. *Craig Tankersley, Joplin, Missouri*; to retain voting shares of Southwest Missouri Bancorporation, Inc., and thereby indirectly retain voting shares of Southwest Missouri Bank, both of Carthage, Missouri.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025-21562 Filed 11-26-25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Information collection notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve an extension, without change, of the currently approved "AHRQ Consumer Assessment of Healthcare Providers and Systems (CAHPS) Home and Community-Based Services Survey (HCBS) Database" (OMB Control number 0935-0245, last approved on January 3, 2023, for three years).

DATES: Comments on this notice must be received by January 27, 2026.

ADDRESSES: Written comments should be submitted to: Margie Shofer, Reports Clearance Officer, AHRQ, by email at REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Margie Shofer, AHRQ Reports Clearance Officer, (301) 427-1696, or by email at REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

The CAHPS Home and Community-Based Services Survey (HCBS-CAHPS Survey) is the first cross-disability survey of home and community-based service beneficiaries' experience receiving long-term services and supports. It is designed to facilitate comparisons across state Medicaid HCBS programs throughout the country that target adults with disabilities, e.g., including older adults, individuals with physical disabilities, persons with developmental or intellectual disabilities, those with acquired brain injury and persons with severe mental illness.

The HCBS-CAHPS Database serves as a primary source of data available to states, agency programs and researchers to help answer important questions related to beneficiary experiences. AHRQ, through its contractor, collects and make available de-identified survey data, enabling HCBS programs to identify areas where quality can be improved.

The HCBS-CAHPS Database supports AHRQ's goals of promoting improvements in the quality and patient-centeredness of health care in home or community-based care settings.

The HCBS-CAHPS Survey was developed by the Centers for Medicare & Medicaid Services (CMS) for voluntary use by state Medicaid programs, including both fee-for-service HCBS programs as well as managed long-term services and supports (MLTSS) programs. States with adequate sample sizes may consider using survey metrics in value-based purchasing initiatives.

This research seeks to answer the following questions:

1. What are the key drivers of patient experience in HCBS programs?
2. How do beneficiary experiences with HCBS vary across states and program types?

3. What are the highest and lowest scoring measures in specific domains of HCBS delivery of care?

This research has the following goals:

1. Produce aggregated results from HCBS–CAHPS survey users that voluntarily submit their data; and
2. Provide feedback reports to HCBS–CAHPS survey users that voluntarily submit their data to help them identify their strengths and areas for improvement in patient care.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement [42 U.S.C 299a(a)(1), (2) and (8)].

The development and operation of the HCBS–CAHPS Database will include the following major components undertaken by AHRQ through its contractor.

1. Program Recruitment. Outreach will be conducted with the HCBS–CAHPS user community (including state agencies, managed long-term services and supports (MLTSS) programs, centers for independent living, improvement collaborative organizations, survey vendors, etc.) to promote the database and its benefits and encourage voluntary contributions of survey data. A variety of communications will be used (*e.g.*, GovDelivery announcements, personal email messages, conference and meeting presentations, etc.) to present the value case for the database and key dates and details about submitting data.

2. Data Submission Platform. AHRQ's contractor currently provides a web-based user-friendly submission platform for both the CAHPS Health Plan and CAHPS Child Hospital survey data. This platform was used as a model to develop the HCBS–CAHPS Database submission system, including data submission specifications; technical assistance and step-by-step instructions for participation; analysis programs for data cleaning and reporting; and data use agreements to protect the confidentiality of the participating organizations and their data.

3. Submission Notifications and Instructions. Clear instructions and notifications are of paramount importance for successful submission of valid data, seamless report dissemination, and streamlined communication with survey vendors, state programs, or other submitters.

Method of Collection

The development and operation of the HCBS–CAHPS Database will include the following data collection activities:

- Registration with the site to obtain an account with a secure username and password;
- Submission of DUAs and survey questionnaires;
- Submission of program information form;
- Submission of de-identified survey data files,
- Generation of status reports indicating that submitted files are either accepted or rejected; and
- Follow-up with submitters in the event of a rejected file, to assist in making corrections and resubmitting the file.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the respondents to participate in the database. The 51 POCs in Exhibit 1 represent the 51 states or agencies that will administer the Adult HCBS survey. An estimated thirteen survey vendors will assist them.

Each POC will:

1. Register online for submission. The online registration form will require about five minutes to complete.

2. Complete a program information form of information about each program such as the name of the program, program size, state, etc. The online program information form takes on average 5 minutes to complete.

3. Complete a DUA. The DUA requires about 3 minutes to sign and return by fax or mail.

Each submitter, which in most cases will be the survey vendor performing the data collection, will provide a copy of their questionnaire and the survey data file in the required file format. Survey data files must conform to the data file layout specifications provided by the HCBS–CAHPS Database. Since the unit of analysis is at the program level, submitters will upload one data file per program. Once a data file is uploaded the file will be automatically checked to ensure it conforms to the specifications and a data file status report will be produced and made available to the submitter. Submitters will review each report and will be expected to correct any errors in their data file and resubmit if necessary. It will take about one hour to submit the data for each program.

The total burden is estimated to be 63 hours annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs *	Number of responses per POC	Hours per response	Total burden hours
Registration Form	51	1	5/60	4.25
Program Information Form	51	1	5/60	4.25
Data Use Agreement	51	1	3/60	2.5
Data Files Submission	13	4	1	52
Total	NA	NA	NA	63

* The 51 POC's for the registration form, program information form and the DUA are the estimated POC's from the estimated participating programs.

Exhibit 2 shows the estimated annualized cost burden based on the

respondents' time to complete one

submission process. The cost burden is estimated to be \$6,940 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Total burden hours	Average hourly wage rate *	Adjusted hourly wage rate **	Total cost burden
Registration Form	4.25	^a 66.22	132.44	\$563
Program Information Form	4.25	^a 66.22	132.44	563
Data Use Agreement	2.5	^b 126.41	252.82	632
Data Files Submission	52	^c 49.83	99.66	5,182
Total	63	NA	NA	6,940

* National Compensation Survey: Occupational wages in the United States May 2024, “U.S. Department of Labor, Bureau of Labor Statistics.”

** The Adjusted Hourly Rate was estimated at 200% of the hourly wage.

^a Based on the mean hourly wage for Medical and Health Services Managers (11–9111).

^b Based on the mean hourly wage for Chief Executives (11–1011).

^c Based on the mean hourly wages for Computer Programmers (15–1251).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ’s information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ’s health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 24, 2025.

Mamatha Pancholi,
Deputy Director.

[FR Doc. 2025–21348 Filed 11–26–25; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4210–N2]

Medicare Program; Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Final Guidance

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing the availability of CMS’ final guidance for the third cycle of the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”), the first cycle of renegotiation, and manufacturer effectuation of the maximum fair price (MFP) in 2026, 2027, and 2028 for the implementation of the Inflation Reduction Act of 2022 (IRA) (*Pub. L. 117–169*). This and other IRA-related guidance can be viewed on the dedicated IRA section of the CMS website at <https://www.cms.gov/inflation-reduction-act-and-medicare/>. **ADDRESSES:** Inquiries related to the final guidance should be sent to IRAREbateandNegotiation@cms.hhs.gov with the subject line, “Medicare Drug Price Negotiation Program Final Guidance.”

FOR FURTHER INFORMATION CONTACT: Elisabeth Daniels, 410–786–0549.

SUPPLEMENTARY INFORMATION: The IRA was signed into law on August 16, 2022. Sections 11001 and 11002 of the IRA established the Negotiation Program to negotiate MFPs for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (the Act) as added by sections 11001 and 11002 of the IRA. On July 4, 2025, the “Working Families Tax Cuts Act” (*Pub. L. 119–21*) was signed into law. Section 71203 of the “Working Families Tax Cuts Act” expanded protections for orphan drugs in section 1192(e) of the Act. The final guidance describes how CMS will implement the Negotiation Program for Initial Price Applicability Year (IPAY) 2028 (January 1, 2028 to December 31, 2028), which includes renegotiation, and specifies the requirements for manufacturer effectuation of the MFPs in 2026, 2027, and 2028.

To obtain copies of this Negotiation Program final guidance and other IRA-related documents, please access the CMS IRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/inflation-reduction-act-and-medicare>. If interested in receiving CMS IRA updates by email, individuals may sign up for CMS IRA’s email updates at <https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates>.

The Administrator of CMS, Dr. Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,
Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–21501 Filed 11–26–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Matching Program; Correction

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) published a notice of a new (re-established) matching program in the **Federal Register** of November 18, 2025, describing a matching program between CMS and State-Based Administering Entities (AEs), titled “Determining Eligibility for Enrollment in Applicable State Health Subsidy Programs Under

the Patient Protection and Affordable Care Act.” The notice failed to include a plain-language description of the matching program in the Summary, stated incorrect dates, and mistakenly used the term “return information” instead of “Federal Tax Information (FTI)” consistently throughout.

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact: Robert Yates, Deputy Director, Division of State and Grant Operations, State Marketplace and Insurance Programs Group, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD 21224, or by email to Robert.Yates@cms.hhs.gov, or Jenny Chen, Director, Division of State Technical Assistance, State Marketplace and Insurance Programs Group, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, 7501 Wisconsin Ave., Bethesda, MD 20814, or by email to Jenny.Chen@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 18, 2025, in FR Doc. 2025–20058, on page 51764, in the first column, correct the “Summary” caption to read: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is providing notice of the re-establishment of a matching program between CMS and State-Based Administering Entities (AEs), titled “Determining Eligibility for Enrollment in Applicable State Health Subsidy Programs Under the Patient Protection and Affordable Care Act (PPACA).” The matching program provides AEs with data CMS receives from federal agencies under other matching programs to use in determining individuals’ eligibility for enrollment in state health subsidy programs under the Patient Protection and Affordable Care Act and to avoid dual enrollments.

In the **Federal Register** of November 18, 2025, in FR Doc. 2025–20058, on page 51764, in the first and second columns, correct the “Dates” caption to read: The deadline for comments on this notice is December 29, 2025. The re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (from approximately

January 2026 to July 2027) and, within three months of expiration, may be renewed for up to one additional year if the parties make no changes to the matching program and certify that the program has been conducted in compliance with the matching agreement.

In the **Federal Register** of November 18, 2025, in FR Doc. 2025–20058, on page 51765, in the first column, correct the “Categories of Records” caption to read: The categories of records that will be used in the matching program are identifying records; minimum essential coverage period records; Federal Tax Information (FTI) (household income and family size information); citizenship status records; birth and death information; disability coverage and income information; and imprisonment status records. The data elements CMS will receive from AEs may include: Social Security Number (if applicable), Last Name, First Name, and Date of Birth. The data elements the AEs will receive from CMS may include: Validation of SSN; Verification of citizenship or immigration status; Incarceration status; Eligibility and/or enrollment in certain types of MEC; Income, based on FTI, Title II benefits, and current income sources; Quarters of Coverage; and Death Indicator.

Barbara Demopoulos,

Privacy Act Officer, Division of Security, Privacy Policy and Governance, Office of Information Technology, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–21394 Filed 11–26–25; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10500 and CMS–10344]

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 January 27, 2026.

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**).

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: Revision with change of a currently approved collection; **Title of Information Collection:** National Implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS); **Use:** The Agency for Healthcare Research and Quality (AHRQ) and its Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Consortium, in conjunction with the Centers for Medicare & Medicaid Services (CMS), have developed standardized CAHPS Surveys and tools for a variety of patient populations, including commercially insured ambulatory patients, patients whose care is covered by Medicare and Medicaid, dialysis patients, home health patients, hospital inpatients, dental patients, and patients who receive behavioral health care and services. The purpose of the CAHPS family of surveys is to collect data about patients’ assessment and rating of the care they receive from their health care provider or health care system.

The national implementation of OAS CAHPS is designed to allow third-party, CMS-approved survey vendors to administer OAS CAHPS using mail-only, telephone-only, mixed mode (mail with telephone follow-up), mixed-mode (web with mail follow-up), or mixed-mode (web with telephone follow-up). The CMS-approved survey vendors who administer the survey use an electronic data collection system if they administer a telephone-only or mixed-mode survey using web. **Form Number:** CMS–10500 (OMB control number: 0938–1240); **Frequency:** Once; **Affected Public:** Business or other for-profits and Not-for-profits institutions; **Number of Respondents:** 2,045,727; **Total Annual Responses:** 2,045,727; **Total Annual Hours:** 500,805. (For policy questions

regarding this collection contact Memuna Ifedirah 410–786–6849.)

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services; **Use:** Section 1860 D–14 of the Social Security Act (the Act) sets forth requirements for premium and cost-sharing subsidies for low-income beneficiaries enrolled in Medicare Part D. Based on this statute, 42 CFR 423.771, provides guidance concerning limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in Part D plans. 42 CFR 423.771(b) establishes requirements for determining a beneficiary’s eligibility for full subsidy under the Part D program. Regulations set forth in §§ 423.780 and 423.782 outline premium and cost sharing subsidies to which full subsidy eligible are entitled under the Part D program.

Each month CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration (SSA). The SSA sends a monthly file of Supplementary Security Income-eligible beneficiaries to CMS. Similarly, the State Medicaid agencies submit Medicare Modernization Act files to CMS that identify full subsidy beneficiaries. CMS deems the beneficiaries as having full subsidy and auto-assigns these beneficiaries to benchmark Part D plans. Part D plans to receive premium amounts based on the monthly assessments. **Form Number:** CMS–10344 (OMB control number: 0938–1127); **Frequency:** Monthly; **Affected Public:** State, Local, or Tribal Governments and Not-for-profits institutions; **Number of Respondents:** 51; **Total Annual Responses:** 51; **Total Annual Hours:** 612. (For policy questions regarding this collection contact Roland Herrera 410–786–0668.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–21435 Filed 11–26–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10410 and CMS–10137]

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 December 29, 2025.

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:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010; *Use:* The State Medicaid and CHIP agencies will collect all information needed to determine and redetermine eligibility for Medicaid and will transmit information, as appropriate, to other insurance affordability programs. The information collection requirements will assist the public to understand information about health insurance affordability programs and will assist CMS in ensuring the seamless, coordinated, and simplified system of Medicaid and CHIP application, eligibility determination, verification, enrollment, and renewal. *Form Number:* CMS-10410 (OMB control number: 0938-1147); *Frequency:* Occasionally; *Affected Public:* Individuals or households, and State, Local, and Tribal Governments; *Number of Respondents:* 25,500,096; *Total Annual Responses:* 76,500,218; *Total Annual Hours:* 21,266,302. (For policy questions regarding this collection contact: Abby Kahn at 410-786-4321.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2027 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or

through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled “Application Procedures and Contracts with PDP Sponsors.”

The information will be collected under the solicitation of proposals from PDP, MA-PD, Cost Plan, Program of All-Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS-10137 (OMB control number: 0938-0936); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for profits, Not for profits institutions; *Number of Respondents:* 785; *Total Annual Responses:* 402; *Total Annual Hours:* 1,723. (For policy questions regarding this collection contact April Forsythe at 410-786-8493 or April.Forsythe@cms.hhs.gov.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025-21433 Filed 11-26-25; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2025-N-0348]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Center for Devices and Radiological Health Appeals Processes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 29, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0738. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910-0738—Revision

This information collection supports implementation of recommendations found in FDA guidance. As discussed in the document entitled “Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes” (March 2022), there

are various processes by which appeals requests regarding review of decisions or actions by CDRH may be submitted to the Agency. The guidance is available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes>. The guidance document provides general format and content recommendations in this regard, discusses applicable regulations with regard to the timing of such submissions, and describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of

the request, and supporting information. While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of information as recommended in the guidance regarding the appeal request itself, as well as data and information relied on by the requestor in the appeal, will help facilitate timely resolution of the decision under review. We are accounting for burden respondents may incur as a result of these Agency recommendations in this collection request. Additional information about the CDRH appeals process is described in the companion guidance entitled “Center for Devices and Radiological Health (CDRH) Appeals Processes:

Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff” (March 2020), also available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a>.

In the **Federal Register** of July 3, 2025 (90 FR 29563), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDRH Appeals Processes	75	1	75	8	600

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 320 hours and a corresponding increase of 40 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years. A review of prior renewals revealed that additional information about the CDRH appeals process is described in the companion guidance entitled “*Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff*” (March 2020) was omitted in the last approval cycle. This current revision adds this missing guidance to provide clarity and ensure completeness. No other changes affect the scope or burden of this information collection.

Brian Fahey,
Associate Commissioner for Legislation.
[FR Doc. 2025–21320 Filed 11–26–25; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children’s Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2026, Through September 30, 2027

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: The Federal Medical Assistance Percentages (FMAP), Enhanced Federal Medical Assistance Percentages (eFMAP), and disaster-recovery FMAP adjustments for fiscal year 2027 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2026, through September 30, 2027. This notice announces the calculated FMAP rates, in accordance with the Act, that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of Federal matching for state medical assistance (Medicaid), Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Title IV–E Foster Care Maintenance payments, Adoption Assistance payments and Kinship Guardianship

Assistance payments, and the eFMAP rates for the Children’s Health Insurance Program (CHIP) expenditures. Table 1 gives figures for each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. This notice reminds states of adjustments available for states meeting requirements for disproportionate employer pension or insurance fund contributions and adjustments for disaster recovery. At this time, no state qualifies for such adjustments, and territories are not eligible.

DATES: The percentages listed in Table 1 will be effective for each of the four quarter-year periods beginning October 1, 2026, and ending September 30, 2027.

FOR FURTHER INFORMATION CONTACT: Amelia Whitman, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D—Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201, (202) 578–1478.

SUPPLEMENTARY INFORMATION: The Secretary of HHS manages programs under titles IV, XIX and XXI of the Act in each jurisdiction of the United States. Programs under titles I, X, and XIV of the Act operate only in Guam and the Virgin Islands, and a program under title XVI of the Act (Aid to the Aged, Blind, or Disabled) operates only in Puerto Rico. The percentages in this notice apply to state expenditures for

most medical assistance and child health assistance, and assistance payments for certain social services provided under these titles. The Act provides separate terms for Federal matching of administrative costs.

Sections 1905(b) and 1101(a)(8)(B) of the Act require the Secretary of HHS to publish the FMAP rates each year. The Secretary calculates the percentages, using formulas set out in sections 1905(b) and 1101(a)(8), and calculations from the Department of Commerce of average income per person in each state and for the United States (meaning, for this purpose, the fifty states). The final percentages are subject to upper and lower limits specified in section 1905(b) of the Act. The percentages for the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands are specified in statute, and thus are not based on the statutory formula that determines the percentages for the 50 states.

Federal Medical Assistance Percentage (FMAP)

Section 1905(b) of the Act specifies the formula for calculating FMAPs as follows: “Subject to [statutory qualifications], the term ‘Federal medical assistance percentage’ for any state shall be 100 per centum less the state percentage; and the state percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such state bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum[.]”

Section 1905(b) further specifies that the FMAP for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 55 percent.

However, section 5101(b) of Division FF of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) amended section 1905(ff) of the Act to provide that the FMAP for the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 83 percent permanently, and that the FMAP for Puerto Rico shall be 76 percent through September 30, 2027. In addition, we note that the rate that applies for Puerto Rico, the Virgin Islands, and Guam in certain other programs pursuant to section 1118 of the Act is 75 percent. Section 4725(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33) amended section 1905(b) to provide that the FMAP for the District

of Columbia, for purposes of titles XIX and XXI, shall be 70 percent. For the District of Columbia, we note under Table 1 that other rates may apply in certain other programs. The rates for the states, the District of Columbia, and the territories are set out in Table 1, Column 1.

Section 1905(y) of the Act, as added by section 2001(a)(3) of the Patient Protection and Affordable Care Act of 2010 (“Affordable Care Act”) (Pub. L. 111–148), provides for an increase in the FMAP for medical assistance expenditures for newly eligible individuals described in section 1902(a)(10)(A)(i)(VIII) of the Act, as added by the Affordable Care Act (the adult group); “newly eligible” is defined in section 1905(y)(2)(A) of the Act. The FMAP for the adult group is 100 percent for Calendar Years 2014, 2015, and 2016, gradually declining to 90 percent in 2020, where it remains indefinitely. Section 1905 of the Act was further amended by section 9814 of the American Rescue Plan of 2021 (“ARP”) (Pub. L. 117–2), which amended subsections (b) and (ff) and added subsection (ii). Subsection (ii) provides an eight-quarter increase of five percentage points in a qualifying state or territory’s FMAP for a state or territory that begins to cover the adult group after March 11, 2021. Section 1905(ii)(3) of the Act, which was added by Section 9814 of the ARP to define a qualifying state for purposes of this increase, was subsequently amended by Section 71114 of the One Big Beautiful Bill Act (Pub. L. 119–21), which the Department refers to as the “Working Families Tax Cut Legislation,” to end availability of the five percentage point FMAP increase to states that newly cover the adult group on or after January 1, 2026. In addition, section 1905(z) of the Act, as added by section 10201 of the Affordable Care Act, provides that states that offered substantial health coverage to certain low-income parents and nonpregnant, childless adults on the date of enactment of the Affordable Care Act, referred to as “expansion states,” shall receive an enhanced FMAP beginning in 2014 for medical assistance expenditures for nonpregnant childless adults who may be required to enroll in benchmark coverage under section 1937 of the Act. Some of these provisions are discussed in more detail in the proposed rule, “Medicaid Program; Eligibility Changes Under the Affordable Care Act of 2010,” published on August 17, 2011 (76 FR 51148, 51172) and the final rule and interim final rule published on March 23, 2012 (77 FR 17144, 17194). This notice does

not set forth the matching rates for the adult group as specified in section 1905(y) of the Act or the matching rates for nonpregnant, childless adults in expansion states as specified in section 1905(z) of the Act.

Other Adjustments to the FMAP

For purposes of Title XIX (Medicaid) of the Act, the Federal Medical Assistance Percentage (FMAP), defined in section 1905(b) of the Act, for each state beginning with fiscal year 2006, may be subject to an adjustment pursuant to section 614 of the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA), Public Law 111–3.

First, the FMAP is adjusted if a state experiences no growth or positive growth in total personal income and an employer in that state has made a significantly disproportionate contribution to an employer pension or insurance fund. The adjustment involves disregarding the significantly disproportionate employer pension or insurance fund contribution in computing the per capita income for the state (but not in computing the per capita income for the United States). Employer pension and insurance fund contributions are significantly disproportionate if the increase in contributions exceeds 25 percent of the total increase in personal income in that state. A **Federal Register** Notice with comment period was published on June 7, 2010 (75 FR 32182) announcing the methodology for calculating this adjustment; a final notice was published on October 15, 2010 (75 FR 63480).

The second situation arises if a state experiences negative growth in total personal income. Beginning with fiscal year 2006, section 614(b)(3) of CHIPRA specifies that, for the purposes of calculating the FMAP for a calendar year in which a state’s total personal income has declined, the portion of an employer pension or insurance fund contribution that exceeds 125 percent of the amount of such contribution in the previous calendar year shall be disregarded in computing the per capita income for the state (but not in computing the per capita income for the United States).

No Federal source of reliable and timely data on pension and insurance contributions by individual employers and states is currently available. We request that states report employer pension or insurance fund contributions to help determine potential FMAP adjustments for states experiencing significantly disproportionate pension or insurance contributions and states experiencing a negative growth in total

personal income. See also the information described in the January 21, 2014 **Federal Register** notice (79 FR 3385).

Section 1905(aa) of the Act, as amended by section 2006 of the Affordable Care Act, specifies that notwithstanding section 1905(b) of the Act, the FMAP for a “disaster-recovery FMAP adjustment state” is adjusted as described in section 1905(aa)(1) of the Act. The statute defines a “disaster-recovery FMAP adjustment State” as one of the 50 states or District of Columbia for which, at any time during the preceding 7 fiscal years, the President has declared a major disaster under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, under which every county or parish in the state warrant individual and public or public assistance from the Federal Government, and for which the regular FMAP¹ as determined for the fiscal year is less than the FMAP for the preceding

fiscal year by an amount outlined under sections 1905(aa)(2)(A) and (aa)(2)(B) of the Act. This notice does not contain disaster recovery adjustments since no state qualifies as a “disaster-recovery FMAP adjustment state.” See more information described in the December 22, 2010 **Federal Register** notice (75 FR 80501).

Enhanced Federal Medical Assistance Percentage (eFMAP) for CHIP

Section 2105(b) of the Act specifies the formula for calculating the eFMAP rates as follows:

[T]he “enhanced FMAP”, for a state for a fiscal year, is equal to the Federal medical assistance percentage (as defined in the first sentence of section 1905(b)) for the state increased by a number of percentage points equal to 30 percent of the number of percentage points by which (1) such Federal medical assistance percentage for the state, is less than (2) 100 percent; but in no case shall the enhanced FMAP for a state exceed 85 percent.

The eFMAP rates are used in the Children’s Health Insurance Program under title XXI and in the Medicaid program for expenditures for medical assistance provided to certain children as described in sections 1905(u)(2) and 1905(u)(3) of the Act. There is no specific requirement to publish the eFMAP rates. We include them in this notice for the convenience of the states (Table 1, Column 2).

(Catalog of Federal Domestic Assistance Program Nos. 93.558: TANF Contingency Funds; 93.563: Child Support Services; 93.596: Child Care Mandatory and Matching Funds of the Child Care and Development Fund; 93.658: Foster Care Title IV–E; 93.659: Adoption Assistance; 93.769: Ticket-to-Work and Work Incentives Improvement Act (TWWIIA) Demonstrations to Maintain Independence and Employment; 93.778: Medical Assistance Program; 93.767: Children’s Health Insurance Program)

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

TABLE 1—FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2026—SEPTEMBER 30, 2027

[Fiscal Year 2027]

State	Federal medical assistance percentages	Enhanced federal medical assistance percentages
Alabama	72.55	80.79
Alaska	51.37	65.96
American Samoa *	83.00	85.00
Arizona	63.81	74.67
Arkansas	70.52	79.36
California	50.00	65.00
Colorado	50.00	65.00
Connecticut	50.00	65.00
Delaware	60.33	72.23
District of Columbia **	70.00	79.00
Florida	55.43	68.80
Georgia	66.63	76.64
Guam *	83.00	85.00
Hawaii	58.39	70.87
Idaho	67.31	77.12
Illinois	52.91	67.04
Indiana	65.24	75.67
Iowa	63.33	74.33
Kansas	62.50	73.75
Kentucky	71.56	80.09
Louisiana	68.14	77.70
Maine	60.62	72.43
Maryland	50.00	65.00
Massachusetts	50.00	65.00
Michigan	65.70	75.99
Minnesota	51.36	65.95
Mississippi	77.32	84.12
Missouri	64.58	75.21
Montana	60.01	72.01
Nebraska	54.54	68.18
Nevada	59.31	71.52
New Hampshire	50.00	65.00
New Jersey	50.00	65.00

¹ Section 1905(aa)(3) of the Act defines a state’s “regular FMAP” to be the FMAP that would

otherwise apply to the state for the fiscal year, as determined under section 1905(b) and without

regard to section 1905(aa), (y), and (z), and section 10202 of the Affordable Care Act.

TABLE 1—FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2026—SEPTEMBER 30, 2027—Continued
[Fiscal Year 2027]

State	Federal medical assistance percentages	Enhanced federal medical assistance percentages
New Mexico	71.47	80.03
New York	50.00	65.00
North Carolina	64.16	74.91
North Dakota	52.91	67.04
Northern Mariana Islands *	83.00	85.00
Ohio	65.12	75.58
Oklahoma	65.86	76.10
Oregon	58.18	70.73
Pennsylvania	57.41	70.19
Puerto Rico *	76.00	83.20
Rhode Island	57.81	70.47
South Carolina	69.28	78.50
South Dakota	50.56	65.39
Tennessee	63.34	74.34
Texas	58.54	70.98
Utah	61.95	73.37
Vermont	57.76	70.43
Virgin Islands *	83.00	85.00
Virginia	50.02	65.01
Washington	50.00	65.00
West Virginia	74.25	81.98
Wisconsin	61.23	72.86
Wyoming	50.00	65.00

* The Consolidated Appropriations Act, 2023 set the FMAP for American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and Virgin Islands permanently at 83 percent and set the FMAP for Puerto Rico at 76 percent through Fiscal Year 2027. For purposes of section 1118 of the Act, the percentage used under titles I, X, XIV, and XVI will be 75 per centum for Puerto Rico, the Virgin Islands, and Guam.

** The values for the District of Columbia (DC) in the table were set for the state plan under titles XIX and XXI and for capitation payments and disproportionate share hospital (DSH) allotments under those titles. For other purposes, the percentage for DC is 50.00, unless otherwise specified by law.

[FR Doc. 2025–21332 Filed 11–26–25; 8:45 am]

BILLING CODE 4150–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

Date: January 26, 2026.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, Bethesda, MD 20892, 301–435–0904, sara.ahlgren@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21366 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biomedical Imaging Approaches in Health Research.

Date: December 17, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vera A. Cherkasova, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B, Rockledge Drive, Room 2137B, Bethesda, MD 20892, (240) 731-6040, vera.cherkasova@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 21, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21351 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Genetics Study Section.

Date: January 14-15, 2026.

Time: 09:30 a.m. to 04:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Juraj Bies, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1256, biesj@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21504 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Prevention Study Section.

Date: January 15, 2026.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Byung Min Chung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-4056, justin.chung@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844,

93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21566 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: January 20, 2026.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, liuyh@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21586 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pathophysiology of Obesity and Metabolic Disease Study Section.

Date: January 13, 2026.

Time: 09:00 a.m. to 07:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.

Contact Person: Latha Malaiyandi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812Q, Bethesda, MD 20892, (301) 435-1999, malaiyandilm@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21516 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR25-311: Leveraging Network Infrastructure to Conduct Innovative Research.

Date: January 16, 2026.

Time: 11:00 a.m. to 01:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jolanta M. Topczewska, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710-E, Bethesda, MD 20892, 301-867-5309, jolanta.topczewska@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21542 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Reproductive Sciences.

Date: January 21, 2026.

Time: 09:00 a.m. to 06:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Baskaran Thyagarajan, Ph.D., Scientific Review Officer Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800B, Bethesda, MD 20892, (301) 867-5309, thyagarajanb2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21555 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Biology and Development of the Eye Study Section.

Date: January 6-7, 2026

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Robert O'Hagan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 909-6378, ohaganr2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21538 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative and Clinical Endocrinology and Reproduction Study Section.

Date: December 18, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Tori Stone, Ph.D., Scientific Review Officer, Endocrine and Metabolic Systems Review Branch, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, 301-594-7549, tori.stone@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21374 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Immunobiology of Transplantation and Alloimmunity Study Section.

Date: January 14-15, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Anthony D. Foster, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-3297, anthony.foster@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21535 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Institutional Research Training in Endocrinology and Reproductive Biology (T32).

Date: December 19, 2025.

Time: 11:00 a.m. to 03:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Zhuqing Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3G41B, National Institutes of Health/ NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892-9834, (240) 669-5068, zhuqing.li@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 21, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21372 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Mechanisms of Cancer Therapeutics C Study Section.

Date: January 13, 2026.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Gloria Huei-Ting Su, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-496-0465, gloria.su@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21550 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 25-139: Immune Oncology Research (R21).

Date: January 23, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Zhiqiang Zou, Ph.D., MD, Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, 7W242, Bethesda, MD 20892, (240) 276-6372, zouzhiq@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21568 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Oral, Dental and Craniofacial Sciences.

Date: January 16, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, Bethesda, MD 20892, (301) 435-1850, limc4@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21539 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Molecular, Cellular and Developmental Neurosciences Integrated Review Group; Neuronal Communications Study Section.

Date: January 8-9, 2026.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Wenyan Han, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1010D, Bethesda, MD 20892, (301) 594-2337, wenyan.han@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21360 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel: PAR Panel; Complementary and Integrative Health Approaches and Mind and Body Interventions.

Date: January 5–6, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sonia Elena Nanescu, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–8163, sonia.nanescu@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21371 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Research Using Samples and Data from Type 1 Diabetes Clinical Studies.

Date: December 16, 2025.

Time: 11:00 a.m. to 01:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, Bethesda, MD 20892, 301–435–1044, chenhui@csr.nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 21, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21356 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Cell Structure and Function 1 Study Section.

Date: January 8–9, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–3717, jessica.smith6@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21355 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Maximizing Investigators' Research Award C Study Section.

Date: January 29–30, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–8559, jimok.kim@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 21, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21354 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Medical Imaging Research.

Date: January 22, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Debanjan Goswami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 806–H, Bethesda, MD 20892, 301–451–1587, debanjan.goswami@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21580 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cardiovascular Differentiation and Development.

Date: January 20, 2026.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, Bethesda, MD 20892, 301–435–0904, sara.ahlgren@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21362 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Advancing Therapeutics A Study Section.

Date: January 14, 2026.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Maureen Shuh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4097, maureen.shuh@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21549 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Review of Institutional Training Grants in Digestive Diseases and Metabolism.

Date: January 16, 2026.

Time: 01:00 p.m. to 05:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Thomas John O'Farrell, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892, (301) 402-8559, tom.ofarrell@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21548 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrine and Metabolic Systems.

Date: January 28, 2026.

Time: 10:00 a.m. to 05:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jolanta M. Topczewska, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710-E, Bethesda, MD 20892, 301-867-5309, jolanta.topczewska@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21558 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special: Clinical studies and Coordinating Centers.

Date: January 16, 2026.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Nawazish Ali Naqvi, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208-Y, Bethesda, MD 20892-7924, (301) 827-7911, nawazish.naqvi@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21583 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Aging, Neurological, Mental and Behavioral Health.

Date: January 20, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Magnus Azuine, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-7579, magnus.azuine@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844,

93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21375 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Vascular and Hematology Integrated Review Group; Basic Biology of Blood, Heart and Vasculature Study Section.

Date: January 27, 2026.

Time: 8:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Aisha Lanette Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–3527, aisha.walker@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21541 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Therapeutic Development for Developmental, Psychiatric, and Substance Use Disorders.

Date: December 2, 2025.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sue Andersen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–5404, sue.andersen-navalta@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,
Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21577 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Lifestyle Change and Behavioral Health Study Section.

Date: January 16, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Pamela Jeter, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–6401, pamela.jeter@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21373 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Strategies to improve vaccine efficacy.

Date: January 20, 2026.

Time: 10:00 a.m. to 06:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vanitha Sundaresa Raman, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC-9823, Rockville, MD 20852, 301-761-7949, vanitha.raman@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 21, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21352 Filed 11–26–25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Basic and Translational Cancer Research.

Date: January 28, 2026.

Time: 09:00 a.m. to 06:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: David G. Ransom, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W124, National Cancer Institute, NIH, Rockville, MD 20850, 240-276-6351, david.ransom@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21503 Filed 11–26–25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Mechanisms of Cancer Therapeutics A Study Section.

Date: January 8–9, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301-435-3504, tothct@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844,

93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21560 Filed 11–26–25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Cellular Mechanisms in Aging and Development Study Section.

Date: January 8–9, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Beverly Ann Doran, Ph.D., Scientific Review Officer, The Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-0597, beverly.doran@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21537 Filed 11–26–25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships Panel; Neurodevelopment, Oxidative Stress and Synaptic Plasticity.

Date: January 13, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Baila Sara Hall, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Blvd. Suite 401, Bethesda, MD 20892, 301-443-9285, baila.hall@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21361 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Integrative Myocardial Physiology/Pathophysiology B Study Section.

Date: January 16, 2026.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kirk E. Dineley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 806E, Bethesda, MD 20892, 301-867-5309, dineleyke@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21574 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics in Genetics of Diseases and Therapeutic Approaches.

Date: January 15, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dharmendar Rathore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 912-D, Bethesda, MD 20892, 301-496-6431, dharmendar.rathore@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21378 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Academic-Industrial Partnerships for Translation of Technologies.

Date: January 8, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Susan Lynn Spence, Ph.D., Scientific Review Officer, Research Technology and, Contract Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Rm. 7W126, National Cancer Institute, Rockville, MD 20850, 301.867.5309, susan.spence@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333,

93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21553 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Nutrition and Metabolism in Health and Disease Study Section.

Date: January 8, 2026.

Time: 09:00 a.m. to 07:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jonathan Michael Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–867–5309, jonathan.peterson@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21533 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Heart, Vascular, and Blood.

Date: January 22, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Devaiah Nanjappa Ballachanda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 801F, Bethesda, MD 20892, (301) 480–0576, ballachandad@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21543 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Endocrinology, Metabolism and Reproduction.

Date: January 7, 2026.

Time: 10:00 a.m. to 05:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dawanna James-Holly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–2776, dawanna.james-holly@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21531 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular and Surgical Devices.

Date: January 7, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Willard Wilson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301-867-5309, willard.wilson@nih.gov.

Registration is not required to attend this meeting.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21369 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Allergy, Immunology, and Transplantation.

Date: January 23, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 240-507-9685, thomas.conway@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21567 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Drug Discovery and Molecular Pharmacology C Study Section.

Date: January 7, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Alireza Seyed Alavi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, ali.alavi@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21573 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mentored Clinical and Basic Sciences.

Date: January 13, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Manoj Kumar Valiyaveetil, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208-R, Bethesda, MD 20817, (301) 402-1616, manoj.valiyaveetil@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21514 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrine and Metabolic Systems Review.

Date: January 7, 2026.

Time: 10:00 a.m. to 05:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institutes of Diabetes & Digestive, National Institutes of Health, 6707 Democracy Blvd., Room 7351, Bethesda, MD 20892, (301) 594-8886, sanovich@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21505 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

Date: January 21-22, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Bruce Daniel Hissong, Ph.D., Scientific Review Officer, Resource and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20850, (240) 276-7752, bruce.hissong@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21547 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review; Group Cellular and Molecular Biology of Glia Study Section.

Date: January 20-21, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sung-Wook Jang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812P, Bethesda, MD 20892, (301) 435-1042, jangs2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333,

93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21534 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

Date: December 18-19, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Caterina Bianco, MD, Ph.D., Chief, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W110, Bethesda, MD 20892, (240) 276-6459, biancoc@mail.nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21381 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: January 21–22, 2026.

Time: 09:00 a.m. to 07:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Anthony Wing Sang Chan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 809K, Bethesda, MD 20892, 301–496–9392, chana3@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21551 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Microbiology and Infectious Diseases.

Date: December 19, 2025.

Time: 09:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Noton K. Dutta, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda MD 20892, 301–594–4163, noton.dutta@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21532 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: January 7–8, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–0229, kenneth.ryan@nih.hhs.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21554 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel RFA Panel; NIH Research Software Engineer (RSE) Award (R50).

Date: January 9, 2026.

Time: 09:30 a.m.–06:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Tianhong Wang, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 809K, Bethesda, MD 20892, 301–594–9259, wangt3@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21367 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Disease Drug Development and Molecular Pharmacology.

Date: January 15–16, 2026.

Time: 10:00 a.m. to 06:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ekaterina Mikhailovna Nestorovich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–1367, ekaterina.nestorovich@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21363 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Hepatology and Toxicology.

Date: January 22, 2026.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Stephanie Nicole Hicks, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–5710, hickssn@mail.nih.gov.

Registration is not required to attend this meeting.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21387 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Cell Biology Study Section.

Date: December 15, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Alyssa Diane Gregory, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–4906, alyssa.gregory@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H Gibson,

Program Specialist Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21383 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.

Date: January 13–14, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Adem Can, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, (301) 435–1042, cana2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21359 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR: Research Education Program.

Date: January 8, 2026.

Time: 11:00 a.m. to 01:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jolanta M. Topczewska, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131B, Bethesda, MD 20892, 301–451–0000, jolanta.topczewska@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21513 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Bacterial-Host Interactions Study Section.

Date: December 18–19, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Uma Basavanna, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–1398, uma.basavanna@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21502 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review, Special Emphasis Panel; RFA Panel: High-Priority Research in Tobacco Regulatory Science.

Date: January 16, 2026.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marilyn Moore-Hoon, Ph.D. Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-9295, mooremarmail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21377 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

Date: January 12, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jennifer Ann Sanders, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-3553, jennifer.sanders@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21576 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Drug and Biologic Disposition and Toxicity Study Section.

Date: January 15-16, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Frederique Yiannikouris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-3313, frederique.yiannikouris@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844,

93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21380 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Par Panel: Pathway to Independence and Research Scientist Development Award (K99/R00, K01 and K25) Review.

Date: December 19, 2025.

Time: 09:30 a.m. to 05:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, mirahamed.hossain@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844,

93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21561 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Career Development.

Date: January 13, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Tushar Baran Deb, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W624, Rockville, MD 20850, 240–276–6132, tushar.deb@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21556 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR23–138: Instrumentation Grant Program for Resource-Limited Institutions (S10).

Date: January 15–16, 2026.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Konrad Jerzy Krzewski, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Room 3G53, Rockville, MD 20852, (240) 747–7526, konrad.krzewski@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21536 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mentored, Career Transition, and Mid-Career K Awards.

Date: January 15, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yasuko Furumoto, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 801–J, Bethesda, MD 20892, 301–827–7835, yasuko.furumoto@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21540 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Basic, Shared, and High-End Instrumentation (S10).

Date: January 30, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mirela Milescu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, mirela.milescu@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21382 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Basic Mechanisms of Diabetes and Metabolism Study Section.

Date: December 17, 2025.

Time: 09:00 a.m. to 07:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Victoria Martinez Virador, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–4703, victoria.virador@nih.gov.

This notice is being published less than 15 days from the meeting date due to

exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 21, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21370 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical and Translational Cancer Research.

Date: January 15, 2026.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Viktoriya Sidorenko, Ph.D., Scientific Review Officer, Cancer Therapeutics Branch, Center for Scientific Review, National Institutes of Health, 9609 Medical Center Drive, Room 7W526, Rockville, MD 20850, 240–276–5073, viktoria.sidorenko@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333,

93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21552 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Innate Immunity B Study Section.

Date: January 07–08, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Bakary Drammeh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805–P, Bethesda, MD 20892, 301–435–0000, drammehbs@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21559 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topic: Neurodegenerative Disease Therapeutics and Diagnostics.

Date: January 22, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Elizabeth Litvina, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1010E, Bethesda, MD 20892, 301-272-0774, liza.litvina@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21384 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-DK-26-009 NI Gateway for T1D Collaborative Research.

Date: January 13, 2026.

Time: 10:00 a.m. to 02:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Joshua Park, Ph.D., Scientific Review Officer, SRB Scientific Review Branch, NIA (National Institute on Aging), 5601 Fishers Lane, Suite 8B, Rockville, MD 20892, (301) 443-7613, joshua.park4@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21545 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Viral Dynamics and Transmission Study Section.

Date: December 16, 2025.

Time: 09:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Alfredo J Guerra, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-2569, alfredo.guerra@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. As a result of the 43-day government shutdown, due to lapsed appropriations, the above meeting was canceled. This meeting was to assess the scientific and technical merit of NIH grant applications, required by statute to disburse NIH funds. The meeting must take place urgently so that evaluations of biomedical research applications addressing multiple major public health priorities can be submitted to the national advisory councils for timely funding recommendations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21499 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Human Studies of Diabetes and Obesity Study Section.

Date: January 27, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Baskaran Thyagarajan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800B, Bethesda, MD 20892, (301) 867-5309, thyagarajanb2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21571 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Vascular and Hematological Systems, Surgical Sciences, Biomedical Imaging, and Bioengineering.

Date: January 22, 2026.

Time: 9:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Courtney Elaine Watkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-3093, courtney.watkins2@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844,

93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21515 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Pathogenic Eukaryotes Study Section.

Date: January 26, 2026.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jennifer Chien Villa, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-496-5436, jennifer.villa@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21570 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

Date: January 8-9, 2026.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Prithi Rajan, Ph.D., Scientific Review Officer, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 6001 Executive Blvd., 5th Floor, MSC 9531, Bethesda, MD 20892, prithi.rajan@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 22, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-21368 Filed 11-26-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: The Cancer Biotherapeutics Development.

Date: January 27, 2026.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Elisaveta Ninova Voynova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 202.934.2336, voynovae@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21582 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Mechanisms of Cancer Therapeutics B Study Section.

Date: January 14, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Maria Dolores Arjona Mayor, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 806D, Bethesda, MD 20892, 301–827–8578, dolores.arjonamayor@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21544 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Lung and Sleep.

Date: January 13, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Melissa H. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Room 207–K, Bethesda, MD 20892, 301–827–7951, nagelinmh2@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 24, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–21517 Filed 11–26–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0200]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0099

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: 1625–0099, Requirements for the Use of Liquefied Petroleum Gas and Compressed Natural Gas as Cooking Fuel on Passenger Vessels; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0200]. 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–C51–P), 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 (571) 607–4058, 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., 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–2025–0200, and must be received by December 29, 2025.

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. 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: 1625–0099.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 40616, August 20, 2025) required by 44 U.S.C. 3506(c)(2). That notice received one unrelated comment. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Requirements for the Use of Liquefied Petroleum Gas and Compressed Natural Gas as Cooking Fuel on Passenger Vessels.

OMB Control Number: 1625–0099.

Summary: The collection of information requires passenger vessels to post two placards that contain safety and operating instructions on the use of cooking appliances that use liquefied gas or compressed natural gas.

Need: 46 U.S.C. 3306(a)(5) and 4302 authorizes the Coast Guard to prescribe regulations for the use of vessel stores of a dangerous nature. These regulations are prescribed in both uninspected and inspected passenger vessel regulations.

Forms: None.

Respondents: Owners and operators of passenger vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 7,232 hours to 7,858 hours a year, due to an increase in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,
(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21483 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0198]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0039

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: 1625–0039, Declaration of Inspection Before Transfer of Liquid Cargo in Bulk; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0198]. 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–C5I–P), 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 (571) 607–4058, 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., 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–2025–0198, and must be received by December 29, 2025.

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. 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: 1625–0039.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 41091, August 22, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Declaration of Inspection Before Transfer of Liquid Cargo in Bulk.

OMB Control Number: 1625–0039.

Summary: A Declaration of Inspection (DOI) documents the transfer of oil and hazardous materials, to help prevent spills and damage to a facility or vessel. Persons-in-charge of the transfer operations must review and certify compliance with procedures specified by the terms of the DOI.

Need: 33 U.S.C. 1321(j) authorizes the Coast Guard to establish regulations to prevent the discharge of oil and hazardous material from vessels and facilities. The DOI regulations appear at 33 CFR 156.150 and 46 CFR 35.35–30.

Forms: None.

Respondents: Persons-in-charge of transfers.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 80,051 hours to 83,196 hours a year, due to an increase in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,
(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21464 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0244]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0105

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: 1625–0105, Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Coast Guard Heartland District and the Illinois Waterway, Coast Guard Great Lakes District; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0244]. 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–C5I–P), 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 (571) 607–4058, 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., 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–2025–0244, and must be received by December 29, 2025.

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. 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: 1625–0105.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 40612, August 20, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Coast Guard Heartland District and the Illinois Waterway, Coast Guard Great Lakes District.

OMB Control Number: 1625–0105.

Summary: The Coast Guard requires position and intended movement reporting, and fleeting operations reporting, from barges carrying certain dangerous cargoes (CDCs) in the inland rivers within the Heartland and Great Lakes Coast Guard Districts. The reporting requirements are found in 33 CFR 165.830 and 165.921.

Need: This information is used to ensure port safety and security and to ensure the uninterrupted flow of commerce.

Forms: None.

Respondents: Owners, agents, masters, towing vessel operators, or persons in charge of barges loaded with CDCs or having CDC residue operating on the inland rivers located within the Heartland and Great Lakes Coast Guard Districts.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 4 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,
(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21469 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard**

[Docket No. USCG–2025–0195]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0005

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: 1625–0005, Application and Permit to Handle Hazardous Materials; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0195]. 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–C5I–P), 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 (571) 607–4058, 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., 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–2025–0195, and must be received by December 29, 2025.

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. 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: 1625–0005.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 40614, August 20, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Application and Permit to Handle Hazardous Materials.

OMB Control Number: 1625–0005.

Summary: The information is used to ensure the safe handling of explosives and other hazardous materials around ports and aboard vessels.

Need: 46 U.S.C. 70011 and 70034 authorize the Coast Guard to establish standards for the handling, storage, and movement of hazardous materials on a vessel and waterfront facility. Regulations in 33 CFR 126.17, 49 CFR 176.100, and 176.415 prescribe the rules for facilities and vessels.

Forms: CG–4260, Application and Permit to Handle Hazardous Materials.

Respondents: Shipping agents and terminal operators that handle hazardous materials.

Frequency: On Occasion.

Hour Burden Estimate: The estimated burden has increased from 484 hours to 511 hours a year, due to an increase in the estimated number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,
(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21462 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0201]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0104

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: 1625–0104, Barges Carrying Bulk Hazardous Materials; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0201]. 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–C5I–P), 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 (571) 607–4058, 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., 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–2025–0201, and must be received by December 29, 2025.

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. 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: 1625–0104.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 40611, August 20, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Barges Carrying Bulk Hazardous Material.

OMB Control Number: 1625–0104.

Summary: This information is needed to ensure the safe shipment of bulk hazardous liquids in barges. The requirements are necessary to ensure that barges meet safety standards and to ensure that barge's crewmembers have the information necessary to operate barges safely.

Need: 46 U.S.C. 3703 authorizes the Coast Guard to prescribe rules related to the carriage of liquid bulk dangerous cargoes. 46 CFR 151 prescribes rules for barges carrying bulk liquid hazardous materials.

Forms: None.

Respondents: Owners and operators of tank barges.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 27,262 hours a year to 23,827 hours, due to a decrease in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,

(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21471 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0247]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0063

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: 1625–0063, Marine Occupational Health and Safety Standards for Benzene; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0247]. 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–C51–P), 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 (571) 607–4058, 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., 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–2025–0247, and must be received by December 29, 2025.

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. 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: 1625–0063.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 41092, August 22, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Marine Occupational Health and Safety Standards for Benzene.

OMB Control Number: 1625–0063.

Summary: To protect marine workers from exposure to toxic Benzene vapor, the Coast Guard implemented 46 CFR 197 Subpart C.

Need: This information collection is vital to verifying compliance.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 38,165 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,

(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21481 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0144]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0121

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 approval for reinstatement without change of the following collection of information: 1625–0121, United States Coast Guard Academy Introduction Mission Program Application and Supplemental Forms; reinstatement with 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0144]. 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–C5I–P), 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 (571) 607–4058, 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., 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–2025–0144, and must be received by December 29, 2025.

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. 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: 1625–0121.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 37533, August 5, 2025)

required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: United States Coast Guard Academy Introduction Mission Program Application and Supplemental Forms.

OMB Control Number: 1625–0121.

Summary: This collection contains the application and all supplemental forms required to be considered as an applicant to the U.S. Coast Guard Academy Introduction Mission (AIM) Program.

Need: The information is needed to select applicants for participation in a one-week summer recruiting and training program for prospective Cadets interested in attending the U.S. Coast Guard Academy.

Forms:

Online application; High school transcript; Personal reference.

USCGA–AIM1, Travel Update Form.

USCGA–AIM2, Scholarship Request.

USCGA–AIM3, Medical Release Form.

Respondents: Approximately 2,000 applicants apply annually to attend the AIM Program. Approximately 3,000 individuals will submit letters of recommendation for these applicants.

Frequency: Applicants must apply only once per year.

Hour Burden Estimate: The annual burden is estimated at 9,000 hours.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: November 13, 2025.

Bradley E. White,

(Acting) Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2025–21470 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0199]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0065

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: 1625–0065, Offshore Supply Vessels; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0199]. 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–C51–P), 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 (571) 607–4058, 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., 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–2025–0199, and must be received by December 29, 2025.

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. 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: 1625–0065.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 40610, August 20, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Offshore Supply Vessels.

OMB Control Number: 1625–0065.

Summary: 46 U.S.C. 3305 and 3306 authorizes the Coast Guard to prescribe safety regulations. 46 CFR Subchapter L promulgates marine safety regulations for offshore supply vessels (OSV).

Need: The OSV posting/marketing requirements are needed to provide instructions to those onboard of actions to be taken in the event of an emergency. The reporting/recordkeeping requirements verify compliance with regulations without Coast Guard presence to witness routine matters, including OSVs based overseas as an alternative to Coast Guard inspection.

Forms: None.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 718 hours to 695 hours a year, due to a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,

(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21472 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0197]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0052

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: 1625–0052, Nondestructive Testing of Certain Cargo Tanks on Unmanned Barges; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2025–0197]. 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–C5I–P), 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 (571) 607–4058, 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., 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–2025–0197, and must be received by December 29, 2025.

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. 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: 1625–0197.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 40613, August 20, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Nondestructive Testing of Certain Cargo Tanks on Unmanned Barges.

OMB Control Number: 1625–0052.

Summary: The Coast Guard uses the results of nondestructive testing to

evaluate the suitability of older pressure-vessel-type cargo tanks of unmanned barges to remain in service. Such a tank, on an unmanned barge, 30 years old or older is subjected to nondestructive testing once every ten years.

Need: Under 46 U.S.C. 3703, the Coast Guard is responsible for ensuring safe shipment of liquid dangerous cargoes and has promulgated regulations for certain barges to ensure the meeting of safety standards.

Forms: None.

Respondents: Owners of tank barges.

Frequency: Every 10 years.

Hour Burden Estimate: The estimated burden remains 104 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,

(Acting) Chief, Office of Privacy Management,
U.S. Coast Guard.

[FR Doc. 2025–21463 Filed 11–26–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0243]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0122

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: 1625–0122, Cargo Securing Manuals; 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 December 29, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket

number [USCG–2025–0243]. 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–C5I–P), 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 (571) 607–4058, 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., 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–2025–0243, and must be received by December 29, 2025.

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. 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: 1625-0122.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 40610, August 20, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Cargo Securing Manuals.

OMB Control Number: 1625-0122.

Summary: The information is used by the Coast Guard to review/approve new or updated cargo securing manuals (CSM).

Need: 46 U.S.C. 2103 and 3306 authorizes the Coast Guard to establish these regulations. Title 33 CFR 97 prescribes the CSM regulations.

Forms: None.

Respondents: Owners, operators, and masters of certain cargo vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 280 hours to 260 hours a year, due to a decrease in the estimated annual number of CSM submissions.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 31, 2025.

Bradley E. White,

(Acting) Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2025-21468 Filed 11-26-25; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA-2025-0002]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Visitor Request Form

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice of Information Collection; request for comment; This a renewal of existing 11000-39 Visitor Request Form, 1670-0036 that was previously approved on August 05, 2022, with an expiration date of November 30, 2025.

SUMMARY: The Office of the Chief Security Officer (OCSO) within Cybersecurity and Infrastructure Security Agency (CISA) submits the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance. CISA previously published this information collection request (ICR) in the **Federal Register** on August 20, 2025, for a 60-day public comment period. No comments were received by CISA. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until December 29, 2025. Submissions received after the deadline for receiving comments may not be considered.

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.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: Michael A. Washington, Jr., 703-235-1925, Michael.Washington@mail.cisa.dhs.gov.

SUPPLEMENTARY INFORMATION: Public Law 107-296 The Homeland Security Act of 2002, Title II, recognizes the Department of Homeland Security's role in integrating relevant critical infrastructure and cybersecurity information, analyses, and vulnerability assessments (whether such information, analyses, or assessments are provided or produced by the Department or others) in order to identify priorities for protective and support measures by the Department, other agencies of the Federal Government, State and local government agencies and authorities, the private sector, and other entities while maintaining positive control of sensitive information regarding the national infrastructure. In support of this mission, CISA Office of the Chief Security Officer (OCSO) must maintain a robust visitor screening capability. CISA OCSO will collect, using an electronic form, information about each potential visitor to CISA facilities and the nature of each visit. CISA OCSO will use collected information to make a risk-based decision to allow visitor access to CISA facilities. This is an extension of an existing information collection.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: Cybersecurity and Infrastructure Security Agency (CISA) Visitor Request Form.

OMB Number: 1670-0036.

Frequency: Annually.

Affected Public: Private and Public Sector.

Number of Respondents: 20,000.

Estimated Time Per Respondent: 10 minutes.

Total Burden Hours: 3,333 hours.

Total Annual Burden Cost:
\$158,010.66.

Total Government Burden Cost:
\$366,514.16.

Robert J. Costello,

Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2025–21452 Filed 11–26–25; 8:45 am]

BILLING CODE 9111–LF–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2025–0040]

Agency Information Collection Activities: 1670–0048: SAFECOM Nationwide Surveys Generic Clearance

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice of information collection; request for comment; this is a renewal of a previously approved information collection. OMB Control Number: 1670–0048.

SUMMARY: The Emergency Communications Division (ECD) within Cybersecurity and Infrastructure Security Agency (CISA) submits the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance. CISA previously published this information collection request (ICR) in the **Federal Register** on September 25, 2025 for a 60-day public comment period. No comments were received by CISA. The purpose of this notice is to allow additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until December 29, 2025. Submissions received after the deadline for receiving comments may not be considered.

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.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: Antonio Branham, Antonio.Branham@mail.cisa.dhs.gov,

SUPPLEMENTARY INFORMATION: In 2006, Congress passed Public Law 109–295, which included SEC. 671. EMERGENCY COMMUNICATIONS also known as the “21st Century Emergency Communications Act of 2006”. The legislation established the Department of Homeland Security (DHS) Office of Emergency Communications, which was re-designated in 2018 as the Emergency Communications Division (ECD) within the Cybersecurity and Infrastructure Security Agency (CISA), to lead the development and implementation of a comprehensive approach to advancing national interoperable communications capabilities. The following responsibilities were established: 6 U.S.C. 571(c) which requires the DHS Secretary through the ECD Assistant Director to: (4) Conduct extensive, nationwide outreach to support and promote the ability of emergency response providers and relevant government officials to continue to communicate in the event of natural disasters, acts of terrorism, and other man-made disasters; (13) develop and update periodically, as appropriate, a National Emergency Communications Plan (NECP) under section 572 of this title; (14) perform such other duties of the Department necessary to support and promote the ability of emergency response providers and relevant government officials to continue to communicate in the event of natural disasters, acts of terrorism, and other

man-made disasters; and (15) perform other duties of the Department necessary to achieve the goal of and maintain and enhance interoperable emergency communications capabilities. 6 U.S.C. 572(a) requires the Secretary in cooperation with State, local, and tribal governments, Federal departments and agencies, emergency response providers, and the private sector, to develop not later than 180 days after the completion of the baseline assessment under section 573 of this title, and periodically update the NECP.

Lastly, 6 U.S.C. 573 requires the DHS Secretary to conduct an assessment of Federal, State, local, and tribal governments that defines the range of capabilities needed by emergency response providers and relevant government officials, assesses the current available capabilities to meet such communications needs; identify the gaps between such current capabilities and defined requirements; at least every five years. These authorities, in addition to DHS responsibilities through Executive Order 13618 in the area of national security/emergency providers’ communications, require periodic reexamination of nationwide emergency communications capabilities.

To perform these statutory obligations, CISA seeks renewal of its PRA Generic Clearance to maintain flexibility in implementing surveys that are relevant to the current emergency communications environment. To meet the statutory requirements of 6 U.S.C. 573, ECD conducts the SAFECOM Nationwide Survey (SNS) to assess evolving capability needs and gaps and track progress against policy initiatives, status of strategic plans, and major industry or market shifts affecting the emergency communications capability.

The purpose of the SNS is to gather information to assess available emergency communications capabilities and identify gaps and needs for emergency response providers to effectively communicate during all types of natural or man-made hazards. CISA ECD uses this information to complete its statutorily mandated assessment and share the data with all stakeholders that have a role in emergency communications. In order to ascertain this information, the SNS is comprised of a battery of instruments designed and distributed to emergency response disciplines at the federal, state/territorial, tribal, and local (county and municipal) levels of government, as well as the private sector. Methods of administration (questionnaire or interview) and distribution (online web form distributed via email or print forms

distributed by mail) are used as appropriate to meet the needs and preferences of various segments of the target population. The SNS solicits responses regarding issues affecting the emergency communications to determine a jurisdiction's level of communications operability, interoperability, continuity, and security. CISA ECD analyzes the data collected from this general survey to identify major gaps and themes affecting emergency communications across levels of government. This analysis informs the development of supplemental surveys and information collections tailored to specific needs across the emergency response community, as well as future iterations of the Nationwide Baseline Communications Assessment (NCBA), Biennial Progress Report (BPR), National Emergency Communications Plan (NECP), and other products and initiatives that enable ECD to carry out its statutory responsibilities at 6 U.S.C. 571(c).

Findings from the SNS provide invaluable insights that CISA ECD shares with emergency communications partners at all levels of government which assists with: (1) Statewide Communications Interoperability Plan (SCIP) development, (2) Threat and Hazard Identification Risk Analysis (THIRA) development, (3) state-level grant programs and guidance, and (4) funding and resource sharing strategy development.

CISA ECD also conducts supplemental surveys to complete statutorily mandated activities (6 U.S.C. 571(c), 572(a), and 573) and will share the data with relevant emergency communications partners. The SAFECOM supplemental surveys deploy topic-specific or targeted surveys to various emergency response disciplines at the federal, state, territorial, tribal, and local levels of government, as appropriate, as well as the private sector. The instruments solicit responses regarding targeted issues affecting specific segments of the emergency response community. CISA ECD analyzes the data collected from these supplemental surveys to identify changing requirements, mitigate risks, and help further inform the data collected from the SNS.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: Generic Clearance: SAFECOM Nationwide Surveys Generic Clearance.
OMB Number: 1670-0048.

Frequency: Annually.
Affected Public: State, Local, Tribal, and Territorial Governments.
Number of Respondents: 7,215.
Estimated Time Per Respondent: 0.5 hours.
Total Burden Hours: 3,643 hours.
Total Annual Burden Cost: \$179,570.66.
Total Annual Cost to Government: \$168,515.35.

Robert J. Costello,

Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2025-21438 Filed 11-26-25; 8:45 am]

BILLING CODE 9111-LF-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2843-26; DHS Docket No. USCIS-2014-0001]

RIN 1615-ZB70

Termination of the Designation of Haiti for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Notice.

SUMMARY: Through this notice, the Department of Homeland Security (DHS) newly announces that the Secretary of Homeland Security (Secretary) is terminating the designation of Haiti for Temporary Protected Status. Because of interference by a federal district court judge, the designation of Haiti is set to expire on February 3, 2026. After reviewing country conditions and consulting with appropriate U.S. Government agencies, the Secretary determined that Haiti no longer meets the conditions for the designation for Temporary Protected Status. The Secretary, therefore, is newly terminating the Temporary Protected Status designation of Haiti as required by statute. This termination is effective February 3, 2026. After February 3, 2026, nationals of Haiti (and aliens having no nationality who last habitually resided in Haiti) who have been granted Temporary Protected Status under Haiti's designation will no longer have Temporary Protected Status. This determination to terminate the TPS designation for Haiti supersedes the determination announced in the July 1, 2025 notice, "Termination of the Designation of Haiti for Temporary Protected Status."

DATES: The designation of Haiti for Temporary Protected Status is terminated, effective at 11:59 p.m., local time, on February 3, 2026.

FOR FURTHER INFORMATION CONTACT: Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, (240) 721-3000.

SUPPLEMENTARY INFORMATION:

List of Abbreviations

CFR—Code of Federal Regulations
DHS—U.S. Department of Homeland Security
EAD—Employment Authorization Document
FR—Federal Register
FRN—Federal Register Notice
Government—U.S. Government
INA—Immigration and Nationality Act
Secretary—Secretary of Homeland Security
TPS—Temporary Protected Status
UN—United Nations
USCIS—U.S. Citizenship and Immigration Services
U.S.C.—United States Code

What is Temporary Protected Status?

The Immigration and Nationality Act (INA) authorizes the Secretary of Homeland Security, after consultation with appropriate agencies of the U.S. Government, to designate a foreign state (or part thereof) for Temporary Protected Status (TPS) if the Secretary determines that certain country conditions exist. *See* INA sec. 244(b)(1), 8 U.S.C. 1254a(b)(1). The Secretary, in her discretion, may grant Temporary Protected Status to eligible nationals of that foreign state (or aliens having no nationality who last habitually resided in the designated foreign state). *See* INA sec. 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A).

At least 60 days before the expiration of a foreign state's Temporary Protected Status designation or extension, the Secretary—after consultation with appropriate U.S. Government agencies—must review the conditions in the foreign state designated for Temporary Protected Status to determine whether the conditions for the Temporary Protected Status designation continue to be met. *See* INA sec. 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary determines that the conditions in the foreign state continue to meet the specific statutory criteria for the designation, Temporary Protected Status will be extended for an additional period of 6 months or, in the Secretary's discretion, 12 or 18 months. *See* INA sec. 244(b)(3)(A), (C), 8 U.S.C. 1254a(b)(3)(A), (C). If the Secretary determines that the foreign state no longer meets the conditions for Temporary Protected Status designation, the Secretary must terminate the

designation. *See* INA sec. 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B). There is no judicial review of “any determination of the [Secretary] with respect to the designation, or termination or extension of a designation of a foreign state” for Temporary Protected Status. *See* INA sec. 244(b)(5)(A), 8 U.S.C. 1254a(b)(5)(A).

Temporary Protected Status is a temporary immigration benefit granted to eligible nationals of a country designated by the Secretary for Temporary Protected Status under the INA, or to eligible aliens without nationality who last habitually resided in the designated country. During the designation period, Temporary Protected Status beneficiaries are eligible to remain in the United States and may not be removed, so long as they continue to meet the requirements of Temporary Protected Status. In addition, Temporary Protected Status beneficiaries are authorized to work and obtain an Employment Authorization Document (EAD), if requested. Temporary Protected Status beneficiaries may also apply for and be granted travel authorization as a matter of discretion. The granting of Temporary Protected Status does not result in or lead to lawful permanent resident status or any other immigration status.

To qualify for Temporary Protected Status, beneficiaries must meet the eligibility standards at INA section 244(c)(2), 8 U.S.C. 1254a(c)(2) in accordance with the implementing regulations at 8 CFR parts 244 and 1244. When the Secretary terminates a country’s designation, beneficiaries return to the same immigration status or category that they maintained before Temporary Protected Status, if any (unless that status or category has since expired or been terminated), or any other lawfully obtained immigration status or category they received while registered for Temporary Protected Status, as long as it is still valid on the date Temporary Protected Status terminates.

Designation of Haiti for Temporary Protected Status

Haiti was initially designated for Temporary Protected Status on January 21, 2010, based on a determination that there were extraordinary and temporary conditions in Haiti that prevented nationals of Haiti from returning in safety and that permitting such aliens to remain temporarily in the United States would not be contrary to the national interest of the United States.¹ Following

the initial designation, former Secretary Napolitano extended and newly designated Haiti for Temporary Protected Status once, from July 23, 2011 through January 22, 2013, based on extraordinary and temporary conditions.² Thereafter, Temporary Protected Status was extended three more times based on extraordinary and temporary conditions: (1) from January 23, 2013 through July 22, 2014;³ (2) from July 23, 2014 through January 22, 2016;⁴ and (3) from January 23, 2016 through July 22, 2017.⁵ Former Secretary Kelly then granted a six-month extension of Temporary Protected Status from July 23, 2017 through January 22, 2018, but made clear that a further extension appeared unwarranted based on then-current country conditions.⁶ Subsequently, then-Acting Secretary Duke announced the termination of the Temporary Protected Status designation of Haiti effective July 22, 2019.⁷

Despite the law barring judicial review, the termination of Haiti’s 2011 Temporary Protected Status designation was challenged in several lawsuits, and court injunctions required DHS to temporarily continue Temporary Protected Status for Haiti pending a final court order.⁸ Former Secretary Mayorkas then newly designated Haiti on the basis of extraordinary and temporary conditions effective August 3, 2021 through February 3, 2023.⁹ Thereafter, Temporary Protected Status for Haiti was extended and newly designated from February 4, 2023 through August 3, 2024.¹⁰

² Extension and Redesignation of Haiti for Temporary Protected Status, 76 FR 29000 (May 19, 2011).

³ Extension of the Designation of Haiti for Temporary Protected Status, 77 FR 59943 (Oct. 1, 2012).

⁴ Extension of the Designation of Haiti for Temporary Protected Status, 79 FR 11808 (Mar. 3, 2014).

⁵ Extension of the Designation of Haiti for Temporary Protected Status, 80 FR 51582 (Aug. 25, 2015).

⁶ Extension of the Designation of Haiti for Temporary Protected Status, 82 FR 23830 (May 24, 2017).

⁷ Termination of the Designation of Haiti for Temporary Protected Status, 83 FR 2648 (Jan. 18, 2018).

⁸ On Dec. 28, 2023, the U.S. District Court for the Northern District of California dismissed *Ramos v. Nielsen*, No. 18–cv–01554 (N.D. Cal. Dec. 28, 2023). Related litigation in *Bhattarai v. Nielsen*, No. 19–cv–731 (N.D. Cal. Mar. 12, 2019) was consolidated with *Ramos* in August 2023. The court agreed with the government position that subsequent Temporary Protected Status designations rendered the pending litigation moot.

⁹ Designation of Haiti for Temporary Protected Status, 86 FR 41863 (Aug. 3, 2021).

¹⁰ Extension and Redesignation of Haiti for Temporary Protected Status, 88 FR 5022 (Jan. 26, 2023).

In July 2024, DHS issued a notice stating that Secretary Mayorkas had once again determined to extend and newly designate Haiti for Temporary Protected Status for an 18-month period, set to expire on February 3, 2026.¹¹ On February 24, 2025, DHS published a **Federal Register** notice announcing the Secretary’s decision to partially vacate the July 1, 2024 Temporary Protected Status decision by reducing the period of extension and new designation of Temporary Protected Status for Haiti from 18 months to 12 months with an amended end date of August 3, 2025.¹² On July 1, 2025, DHS published a **Federal Register** notice announcing the Secretary’s decision to terminate the Temporary Protected Status designation for Haiti, effective September 2, 2025.¹³

Again, in spite of the statute prohibiting judicial review, on July 15, 2025, a judge in the U.S. District Court for the Eastern District of New York issued a final judgment in *Haitian Evangelical Clergy Ass’n v. Trump*, No. 25–cv–1464, that makes the effective date of any termination no earlier than February 3, 2026. In compliance with the U.S. District Court for the Eastern District of New York’s final judgment, the current Temporary Protected Status designation period for Haiti ends February 3, 2026. In view of the district court’s ruling with respect to the partial vacatur, the Secretary made a new, superseding determination under 8 U.S.C. 1254a(b)(3)(A), which is being announced in this notice.

Secretary’s Authority To Terminate the Designation of Haiti for Temporary Protected Status

At least 60 days before the expiration of a foreign state’s Temporary Protected Status designation or extension, the Secretary—after consultation with appropriate U.S. Government agencies—must review the conditions in the foreign state designated for Temporary Protected Status to determine whether the country continues to meet the conditions for the designation. *See* INA sec. 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary determines that the foreign state no longer meets the conditions for the Temporary Protected Status designation, the Secretary must terminate the designation. *See* INA sec. 244(b)(3)(B), 8

¹¹ Extension and Redesignation of Haiti for Temporary Protected Status, 89 FR 54484 (July 1, 2024).

¹² Partial Vacatur of 2024 Temporary Protected Status Decision for Haiti, 90 FR 10511 (Feb. 24, 2025).

¹³ Termination of the Designation of Haiti for Temporary Protected Status, 90 FR 28760 (July 1, 2025).

¹ Designation of Haiti for Temporary Protected Status, 75 FR 3476 (Jan. 21, 2010).

U.S.C. 1254a(b)(3)(B). The termination may not take effect earlier than 60 days after the date the **Federal Register** notice of termination is published, or if later, the expiration of the most recent previous extension of the country designation. *See id.* The Secretary may determine the appropriate effective date of the termination and expiration of any Temporary Protected Status-related documentation, such as EADs, issued or renewed after the effective date of termination. *See id.*; *see also* INA sec. 244(d)(3), 8 U.S.C. 1254a(d)(3) (providing the Secretary the discretionary “option” to allow for a certain “orderly transition” period if she determines it to be “appropriate”).

Reasons for the Secretary’s Termination of the Temporary Protected Status Designation for Haiti

Consistent with INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A), after consulting with appropriate U.S. Government agencies, the Secretary reviewed country conditions in Haiti and considered whether Haiti continues to meet the conditions for the designation under INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C). This review included examining: (a) whether extraordinary and temporary conditions in Haiti that prevent aliens who are Haitian nationals from returning to Haiti in safety continued to exist, and (b) if permitting Haitian nationals to remain temporarily in the United States was contrary to the national interest of the United States.

Based on the Department’s review, the Secretary has determined that there are no extraordinary and temporary conditions in Haiti that prevent Haitian nationals (or aliens having no nationality who last habitually resided in Haiti) from returning in safety. Moreover, even if the Department found that there existed conditions that were extraordinary and temporary that prevented Haitian nationals (or aliens having no nationality who last habitually resided in Haiti) from returning in safety, termination of Temporary Protected Status of Haiti is still required because it is contrary to the national interest of the United States to permit Haitian nationals (or aliens having no nationality who last habitually resided in Haiti) to remain temporarily in the United States.

Certain conditions in Haiti remain concerning. As an example of the challenges still facing the country, during his August 28, 2025 address to the United Nations (UN) Security Council, the UN Secretary-General reported that 1.3 million people—approximately 12% of Haiti’s

population—have been forced to flee their homes and are internally displaced due to escalating violence and gang violence that has “engulfed” Port-au-Prince “and spreads beyond.”¹⁴ At the UN Security Council briefing on Haiti on August 28, 2025, the Acting U.S. Ambassador to the UN, Dorothy Shea, commented that “the United States remains concerned about escalating levels of violence in Haiti” and “the territorial expansion of the gangs threatens to undermine gains made by both the Haitian National Police and the Multinational Security Support mission.”¹⁵ During the most recent UN Security Council briefing on Haiti on October 22, 2025, U.S. Ambassador to the UN Mike Waltz¹⁶ likewise acknowledged that Haiti “has had a long and difficult history” and “truly stands at a crossroad.”¹⁷ Ambassador Waltz further stated: “We have gangs that are terrorizing communities, extorting families, recruiting children to commit horrors on behalf of the gang leaders. The spillover effects of this violence threaten not only Haiti but the stability of the wider Caribbean and the Western Hemisphere.”¹⁸

The data surrounding internal relocation does indicate parts of the country are suitable to return to. There have also been some other positive developments. For example, in a recent briefing, the UN Secretary General stated that despite continuing violence in Haiti, “there are emerging signals of hope.”¹⁹ On September 30, 2025, the UN Security Council approved a resolution which authorized a new multinational Gang Suppression Force to replace the Kenyan-led security support mission. Per the UN, “under an initial 12-month mandate, the GSF

[Gang Suppression Force] will work in close coordination with the Haitian National Police (HNP) and the Haitian armed forces to conduct intelligence-led operations to neutraliz[e] gangs, provide security for critical infrastructure and support humanitarian access. The 5,550-strong force will also protect vulnerable groups, support reintegration of former fighters and help strengthen Haitian institutions.”²⁰ On October 1, 2025, Secretary Rubio issued a press statement stating “this force will address Haiti’s immediate security challenges and lay the groundwork for long-term stability. . . moving forward, the GSF, with support from the UNSOH [UN Support Office in Haiti], will transition to an international burden-sharing model with the sufficient resources needed to fight the gangs.”²¹ Further, according to the World Bank, “modest GDP growth is projected by 2026 as investment increases from a low baseline, assuming improvements on the political and security fronts.”²²

Based on the Department’s review, the Secretary has determined that while the current situation in Haiti is concerning, the United States must prioritize its national interests and permitting Haitian nationals to remain temporarily in the United States is contrary to the U.S. national interest.

“National interest” is an expansive standard that may encompass an array of broad considerations, including foreign policy, public safety (e.g., potential nexus to criminal gang membership), national security, migration factors (e.g., pull factors), immigration policy (e.g., enforcement prerogatives), and economic considerations (e.g., adverse effects on U.S. workers, impact on U.S. communities).²³ Determining whether

¹⁴ United Nations, “Security-General’s remarks to the Security Council—on Haiti [trilingual, as delivered; scroll down for all-English and all-French],” Aug. 28, 2025, <https://www.un.org/sg/en/content/sg/statement/2025-08-28/secretary-generals-remarks-the-security-council-haiti-trilingual-delivered-scroll-down-for-all-english-and-all-french>.

¹⁵ U.S. Mission to the UN, “Remarks at a UN Security Council Briefing on Haiti” (Aug. 28, 2025) (further highlighting humanitarian concerns such as displacement, recruitment of children in armed gangs, and food insecurity), <https://ht.usembassy.gov/remarks-at-a-un-security-council-briefing-on-haiti/>.

¹⁶ Ambassador Waltz was officially sworn in as the U.S. Representative to the UN on September 20, 2025.

¹⁷ U.S. Mission to the UN, “Remarks at a UN Security Council Briefing on Haiti” (Oct. 22, 2025), <https://usun.usmission.gov/remarks-at-a-un-security-council-briefing-on-haiti-8/>.

¹⁸ *Id.*

¹⁹ United Nations, “‘The people of Haiti are in a perfect storm of suffering,’ warns UN chief,” Aug. 28, 2025, <https://news.un.org/en/story/2025/08/1165738>.

²⁰ United Nations, “UN Security Council approves new ‘suppression force’ for Haiti amid spiraling gang violence,” Sept. 30, 2025, <https://news.un.org/en/story/2025/09/1166006>.

²¹ U.S. Dep’t of State, “On the Next Steps to Restoring Security in Haiti,” Oct. 1, 2025, <https://www.state.gov/releases/office-of-the-spokesperson/2025/10/on-the-next-steps-to-restoring-security-in-haiti/>; *see also* U.S. Mission to the UN, “Remarks at a UN Security Council Briefing on Haiti,” (Oct. 22, 2025) (remarks of Ambassador Waltz applauding the adoption of the resolution supporting the GSF), <https://usun.usmission.gov/remarks-at-a-un-security-council-briefing-on-haiti-8/>.

²² World Bank, “The World Bank in Haiti” (last updated Apr. 28, 2025), <https://www.worldbank.org/en/country/haiti/overview>.

²³ *See, e.g., Poursina v. USCIS*, 936 F.3d 868, 874 (9th Cir. 2019) (observing, in an analogous INA context, “that the ‘national interest’ standard invokes broader economic and national-security considerations, and such determinations are firmly committed to the discretion of the Executive Branch—not to federal courts” (citing *Trump v.*

permitting a class of aliens to remain temporarily in the United States is contrary to the U.S. national interest therefore calls upon the Secretary's expertise and discretionary judgment.

President Trump clearly articulated policy imperatives bearing upon the national interest in his immigration and border-related executive orders and proclamations. In Proclamation 10888 "Guaranteeing the States Protection Against Invasion," President Trump emphasized that Congress has established a complex and comprehensive framework under the INA to regulate the entry and exit of aliens and goods across U.S. borders. Under normal conditions, this framework supports national sovereignty by enabling the admission of aliens whose presence serves the national interest and excluding those who may pose risks to public health, safety, or national security. However, in a high-volume border environment—particularly when the system is overwhelmed—this screening process can become ineffective. Limited access to critical information and significant processing delays hinder the ability of federal officials to reliably assess the criminal histories or national security threats posed by aliens attempting to enter the U.S. illegally. As a result, public safety and national security risks are significantly heightened in such conditions.²⁴

In Executive Order (E.O.) 14161 "Protecting the United States From Foreign Terrorists and Other National Security and Public Safety Threats," President Trump instructed the Secretary of State, Attorney General, Secretary of Homeland Security, and Director of National Intelligence to jointly submit to the President a report that identified countries throughout the world "for which vetting and screening information is so deficient as to warrant a partial or full suspension on the admission of nationals from those countries."²⁵ Proclamation 10949 "Restricting the Entry of Foreign

Nationals to Protect the United States from Foreign Terrorists and Other National Security and Public Safety Threats" built upon the findings of that review. President Trump determined to fully restrict and limit the entry of nationals from Haiti following his review of the requested report. In support of this decision, President Trump outlined that "according to the [Fiscal Year 2023 Entry/Exit] Overstay Report [published on August 5, 2024], Haiti had a B-1/B-2 visa overstay rate of 31.38 percent and an F, M, and J visa overstay rate of 25.05 percent."²⁶ In addition, "as is widely known, Haiti lacks a central authority with sufficient availability and dissemination of law enforcement information necessary to ensure its nationals do not undermine the national security of the United States."²⁷

Overstaying the terms of the nonimmigrant visa is a violation of U.S. immigration laws and presents challenges for immigration enforcement and resource allocation. Visa overstaying diverts resources from other critical enforcement priorities, such as addressing illegal border crossings. According to the Fiscal Year 2024 Department of Homeland Security Entry/Exit Overstay Report [published on July 16, 2025], Haiti had a Non-Visa Waiver Program Countries Business or Pleasure Visitors (B-1/B-2) visa overstay rate of 24.84% and a Student and Exchange Visitors (F, M, J) visa overstay rate of 22.35%.²⁸ These figures significantly exceed the global average overstay rates of 2.33% for B-1/B-2 visas and 3.23% for F, M, J visas—over ten times higher for business or pleasure visitors and six times higher for student and exchange visitors.²⁹ Haiti's visa overstay rates consistently remain very high compared to other nations, reflecting ongoing challenges in enforcing compliance with U.S. visa regulations. Elevated overstay rates present potential risks to U.S. national security and public safety, as aliens who overstay their visas may be harder to locate and monitor, increasing vulnerabilities within immigration enforcement systems. Moreover, aliens

who overstay nonimmigrant visas can place an added strain on local communities by increasing demand for public resources, contributing to housing and healthcare pressures, and competing in an already limited job market.

In E.O. 14159 "Protecting the American People Against Invasion," President Trump underscored that enforcing the immigration laws "is critically important to the national security and public safety of the United States."³⁰ In furtherance of that objective, the President directed the Secretary, along with the Attorney General and Secretary of State, to promptly take all appropriate action, consistent with law, to rescind policies that led to increased or continued presence of illegal aliens in the United States.³¹ Among the directed actions are to ensure that the Temporary Protected Status designations are consistent with the Temporary Protected Status statute and "are appropriately limited in scope and made for only so long as may be necessary to fulfill the textual requirements of that statute."³²

Prior to FY2025, U.S. Border Patrol recorded a consistent year-over-year increase in encounters with Haitian nationals: 56,596 in FY2022, 163,781 in FY2023, and 220,798 in FY2024.³³ For several years, there has been a significant increase in the number of Haitians arriving in the United States illegally, particularly via land. According to one report, "from 2019 through 2021, Haitians were the top nationality for migrants crossing the dangerous Darien Gap between Colombia and Panama, and they have remained among the three largest groups in 2022 and 2023."³⁴ Another report states: "the continuation of a devastating political, environmental, social, and economic situation. . . in Haiti guarantees an unbroken chain migration, particularly to the United States and Canada; and when combined with already heavy backlogs in processing resident status changes, a large and growing flow of Haitians will

Hawaii, 585 U.S. 667, 684–86 (2018)); *Flores v. Garland*, 72 F.4th 85, 89–90 (5th Cir. 2023) (same); *Brasil v. Sec'y, Dep't of Homeland Sec.*, 28 F.4th 1189, 1193 (11th Cir. 2022) (same); cf. *Matter of D-J*, 23 I&N Dec. 572, 579–81 (A.G. 2003) (recognizing that taking measures to stem and eliminate possible incentives for potential large-scale migration from a given country is "sound immigration policy" and an "important national security interest"); *Matter of Dhanasar*, 26 I&N Dec. 884, 890–91 (AAO 2016) (taking into account impact on U.S. workers in "national interest" assessments).

²⁴ Guaranteeing the States Protection Against Invasion, 90 FR 8333 (Jan. 29, 2025).

²⁵ Protecting the United States From Foreign Terrorists and Other National Security and Public Safety Threats, 90 FR 8451 (Jan. 30, 2025).

²⁶ Restricting the Entry of Foreign Nationals to Protect the United States From Foreign Terrorists and Other National Security and Public Safety Threats, 90 FR 24497 (June 10, 2025).

²⁷ Restricting the Entry of Foreign Nationals to Protect the United States From Foreign Terrorists and Other National Security and Public Safety Threats, 90 FR 24497 (June 10, 2025).

²⁸ U.S. Customs and Border Protection, Entry/Exit Overstay Report, Department of Homeland Security (July 16, 2025), https://www.dhs.gov/sites/default/files/2025-08/25_0826_cbp_entry-exit-overstay-report-fiscal-year-2024.pdf.

²⁹ *Id.*

³⁰ Protecting the American People Against Invasion, 90 FR 8443 (Jan. 29, 2025).

³¹ *Id.*, sec. 16, 90 FR 8446.

³² *Id.*, sec. 16, 90 FR 8446.

³³ U.S. Customs and Border Protection, "U.S. Border Patrol and Office of Field Operations Encounters by Area of Responsibility and Component" (last updated: Sept. 19, 2025), available at: <https://www.cbp.gov/newsroom/stats/nationwide-encounters>.

³⁴ Migration Policy Institute, "Haitian Immigrants in the United States" (Nov. 8, 2023), available at: <https://www.migrationpolicy.org/article/hafrican-immigrants-united-states-2022>.

persist.”³⁵ This pattern of large-scale illegal immigration as a result of “pull factors” has continued for years.

The numerous new designations of Temporary Protected Status for Haiti in 2011, 2021, and 2023, opened eligibility to those who entered and continued to enter the U.S. many years after the initial 2010 designation.³⁶ As noted above, illegal immigration from Haiti into the U.S. continued to increase with extremely high numbers seen around the time of and following the latest new designations of Temporary Protected Status for Haiti by then Secretary Mayorkas.

Approximately 67,400 nationals of Haiti have entered the United States since June 3, 2024. Within this population, approximately 3,000 are nonimmigrants in valid status, approximately 1,000 are nonimmigrants out of status, approximately 63,000 were encountered at a border or port of entry and have no lawful immigration status, and it is estimated that 400 crossed the U.S. border without being apprehended.³⁷ These realities are unsustainable and inconsistent with President Trump’s outlined policy priorities as well as U.S. national interests.

Beyond migration factors and immigration policy, public safety and national security are important considerations when assessing if a Temporary Protected Status designation is in line with U.S. national interests. DHS records indicate that there are Haitian nationals who are Temporary Protected Status recipients who have been the subject of administrative investigations for fraud, public safety, and national security. These issues underscore a conflict with the national interest of the United States.

As acknowledged previously in this notice, gang violence in Haiti persists as armed groups operate with impunity, enabled by a weak or effectively absent central government. The Congressional Research Service described the situation

in Haiti in a recent report: “The gangs—some of which are aligned with political elites—amassed control over territory and illicit markets amid political instability following the 2021 assassination of then-President Jovenel Moise. Since April 2024, Haiti has been governed by a Transitional Presidential Council (TPC). The TPC, tasked with governing until elections can be convened, has been plagued by allegations of corruption and infighting.”³⁸ As such, it has not been able to effectively crack down on gang violence. However, the revamped international efforts and multinational Gang Suppression Force aim to combat gang violence to improve conditions in Haiti. On May 2, 2025, the Secretary of State announced the State Department’s designation of Viv Ansanm and Gran Grif as Foreign Terrorist Organizations and Specially Designated Global Terrorists. In his announcement, the Secretary noted “Haitian gangs, including the Viv Ansanm coalition and Gran Grif, are the primary source of instability and violence in Haiti. They are a direct threat to U.S. national security interests in our region . . . their ultimate goal is creating a gang-controlled state where illicit trafficking and other criminal activities operate freely and terrorize Haitian citizens.”³⁹ In October 2025, Ambassador Waltz said in an interview “we in the UN Security Council just took action yesterday on the gangs that have taken over Haiti, right off Florida’s shores. These gangs are in coordination with all of these transnational groups. They’re shipping drugs, money, weapons. They’re destabilizing the entire region.”⁴⁰

Widespread gang violence in Haiti is sustained by the country’s lack of functional government authority. This breakdown in governance directly impacts U.S. national security interests, particularly in the context of uncontrolled migration. As previously outlined, when immigration flows exceed our capacity to properly vet

aliens at the border, the risks are compounded by the inability to access reliable law enforcement or security information from the alien’s country of origin. The joint assessment by the Secretary of State, Secretary of Homeland Security, and Director of National Intelligence has found that Haiti lacks a functioning central authority capable of maintaining or sharing such critical information, severely limiting the U.S. government’s ability to screen and vet Haitians in the United States with Temporary Protected Status. And Haitian gangs—such as those designated by the State Department as Foreign Terrorist Organizations—pose a serious threat to U.S. interests. These challenges support the determination that permitting Haitian nationals to remain temporarily in the United States is contrary to the national interest.

This lack of government control has not only destabilized Haiti internally but has also had direct consequences for U.S. public safety. Haitian gang members have already been identified among those who have entered the United States and, in some cases, have been apprehended by law enforcement for committing serious and violent crimes. For example, in January 2025, U.S. Immigration and Customs Enforcement (ICE) apprehended Wisteguens Jean Quely Charles, a member of a violent Haitian street gang, who had been arrested, charged and convicted for 17 crimes between August 2022 and August 2024 including both “possession of and possession to distribute controlled substances, distribution of controlled substances, trespassing, carrying dangerous weapon to wit brass knuckles, possession of a firearm without a permit, possession of ammunition without a permit, assault and battery with a dangerous weapon, assault and battery, and resisting arrest.”⁴¹ This case underscores the broader risk posed by rising Haitian migration, particularly in light of multiple large-scale prison breaks in Haiti⁴² and the increasing numbers of

³⁵ IOM, “Engaging the Haitian Diaspora” (Sept 10, 2013), available at: <https://environmentalmigration.iom.int/resources/engaging-haitian-diaspora>.

³⁶ The intent of Temporary Protected Status was to create a temporary safe haven for aliens who are already in the United States. See INA sec. 244(c)(1)(A)(i) (limiting Temporary Protected Status eligibility to aliens continuously physically present in the United States since the country’s designation), (c)(5) (clarifying that a Temporary Protected Status designation does not authorize aliens to come to the United States to apply for such status). Using TPS to grant temporary status to successive waves of new arrivals from a designated country may generate a significant pull factor for illegal immigration and act in tension with the congressional design.

³⁷ Office of Homeland Security Statistics, estimate as of September 30, 2025.

³⁸ Library of Congress, Congressional Research Service, “Haiti in Crisis: Developments Related to the Multinational Security Support Mission” (June 3, 2025), available at: <https://www.congress.gov/crs-product/IN12331#:~:text=Between%20January%20and%20March%202025,attributed%20to%20gang%20related%20violence>.

³⁹ U.S. Department of State, “Terrorist Designations of Viv Ansanm and Gran Grif” (May 2, 2025), available at: <https://www.state.gov/releases/office-of-the-spokesperson/2025/05/terrorist-designations-of-viv-ansanm-and-gran-grif/>.

⁴⁰ U.S. Mission to the UN, “U.S. Representative to the United Nations, Ambassador Mike Waltz’s Interview with Martha Maccallum on Fox News” (Oct. 1, 2025), <https://usun.usmission.gov/u-s-representative-to-the-united-nations-ambassador-mike-waltz-interview-with-martha-maccallum-on-fox-news/>.

⁴¹ U.S. Immigration and Customs Enforcement, “ICE ERO Boston arrests Haitian gang member with numerous convictions” (Jan. 24, 2025), available at: <https://www.ice.gov/news/releases/ice-ero-boston-arrests-haitian-gang-member-numerous-convictions>.

⁴² See The Guardian “Haiti declares state of emergency after thousands of dangerous inmates escape” (Mar. 4, 2024) (“Haiti has declared a three-day state of emergency and a night-time curfew after armed gangs stormed the country’s two biggest jails, allowing more than 3,000 dangerous criminals, including murderers and kidnappers, to escape back on to the streets of the poor and violence-racked Caribbean nation.”), available at: <https://www.theguardian.com/world/2024/mar/04/>

encounters reported by U.S. Customs and Border Protection. The inability of the previous administration to reliably screen aliens from a country with limited law enforcement infrastructure and widespread gang activity presents a clear and growing threat to U.S. public safety.

Moreover, since the U.S. designated Viv Ansanm and Gran Grif as foreign terrorist organizations, the Department of Homeland Security, Department of Justice, and Department of State have announced arrests and indictments of aliens linked to these gangs. These actions demonstrate that these groups pose not just an overseas threat but a tangible national security and public safety risk within our borders. In addition, that these aliens were able to operate inside the United States raises serious concerns about how they entered or remained in the United States, potentially due to inadequate screening at the border or a lack of actionable intelligence from Haitian authorities on known gang affiliates. In July 2025, State announced deportation actions against U.S. lawful permanent residents who were found to be affiliated with Viv Ansanm.⁴³ In September 2025, ICE announced the arrest of a Haitian alien who “engaged in a campaign of violence and gang support that contributed to Haiti’s destabilization.”⁴⁴

In E.O. 14150 “America First Policy Directive to the Secretary of State,” President Trump declared “from this day forward, the foreign policy of the United States shall champion core

American interests and always put America and American citizens first.” Moreover, it instructed “as soon as practicable, the Secretary of State shall issue guidance bringing the Department of State’s policies, programs, personnel, and operations in line with an America First foreign policy, which puts America and its interests first.”⁴⁵ As mentioned, the UN Security Council adopted a resolution to transition the Multinational Security Support mission to a Gang Suppression Force and authorized the establishment of a UN Support Office in Haiti.⁴⁶ On October 1, 2025, Secretary Rubio released a press statement commending the adoption of the resolution: “The message from the Security Council is clear: the era of impunity for those who seek to destabilize Haiti is over. The United States remains committed to working with international stakeholders to support Haiti’s path toward peace, stability, and democratic governance. We call on all nations to join us in this critical effort.”⁴⁷ Ending Temporary Protected Status for Haiti reflects a necessary and strategic vote of confidence in the new chapter Haiti is turning. The United States cannot call for bold change on the ground while signaling doubt from afar. Our immigration policy must align with our foreign policy vision of a secure, sovereign, and self-reliant Haiti and not a country that Haitian citizens continue to leave in large numbers to seek opportunities in the United States.

In summary, the current situation in Haiti is concerning. However, the United States must prioritize its national interests, which includes assessing foreign policy, public safety, national security, migration factors, immigration policy, and economic considerations. In considering these factors individually and cumulatively, the Secretary has determined that permitting Haitian nationals to remain temporarily in the United States is contrary to the U.S. national interest.

DHS estimates that there are approximately 352,959 nationals of Haiti (and aliens having no nationality who last habitually resided in Haiti) who hold Temporary Protected Status under Haiti’s designation.⁴⁸

Effective Date of Termination of the Designation

The Temporary Protected Status statute provides that the termination of a country’s Temporary Protected Status designation may not be effective earlier than 60 days after the notice is published in the **Federal Register** or, if later, the expiration of the most-recent previous extension. *See* INA sec. 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B).

The Temporary Protected Status statute authorizes the Secretary, at her discretion, to allow for an “orderly transition” period with respect to the termination and the expiration of any Temporary Protected Status-related documentation, such as EADs. The Secretary has determined, in her discretion, that the statutory minimum transition period of 60 days is sufficient and warranted here given the Secretary’s finding that continuing to permit Haitian nationals to remain temporarily in the United States is contrary to the U.S. national interest. *See* INA sec. 244(d)(3), 8 U.S.C. 1254a(d)(3).⁴⁹ Accordingly, the termination of the Haiti Temporary Protected Status designation will be effective February 3, 2026.⁵⁰

DHS recognizes that Haiti Temporary Protected Status beneficiaries under the

no nationality who last habitually resided in Haiti) are also approved as Lawful Permanent Residents. Data queried by Department of Homeland Security, U.S. Citizenship and Immigration Services, Office of Performance and Quality November 2025.

⁴⁹ Whether to allow for an additional “orderly departure” period following a Temporary Protected Status designation termination (beyond the statutory minimum of 60 days) is an “option” left to the Secretary’s unfettered discretion. INA 244(d)(3), 8 U.S.C. 1254a(d)(3). Although DHS has allowed such extended periods for certain Temporary Protected Status terminations, *see, e.g., Termination of the Designation of Sudan for Temporary Protected Status*, 82 FR 47228 (Oct. 11, 2017) (12-month orderly transition period); *Termination of the Designation of Sierra Leone Under the Temporary Protected Status Program; Extension of Employment Authorization Documentation*, 68 FR 52407 (Sept. 3, 2003) (6-month orderly transition period), certain other Temporary Protected Status designations were terminated without allowing for such transition periods, *see, e.g., Termination of Designation of Angola Under the Temporary Protected Status Program*, 68 FR 3896 (Jan. 27, 2003) (no orderly transition period); *Termination of Designation of Lebanon Under Temporary Protected Status Program*, 58 FR 7582 (Feb. 8, 1993) (same). The Secretary has determined that a 60-day period is appropriate under the circumstances.

⁵⁰ *See* 8 CFR 244.19 (“Upon the termination of designation of a foreign state, those nationals afforded temporary Protected Status shall, upon the sixtieth (60th) day after the date notice of termination is published in the **Federal Register**, or on the last day of the most recent extension of designation by the [Secretary of Homeland Security], automatically and without further notice or right of appeal, lose Temporary Protected Status in the United States. Such termination of a foreign state’s designation is not subject to appeal.”).

haiti-mass-jailbreak-violence-port-au-prince-gangs; Al Jazeera, “Haiti declares curfew after 4,000 inmates escape jail amid rising violence” (Mar. 4, 2024) (“Haiti’s government has declared a state of emergency and imposed a curfew after an explosion of gang-led violence over the weekend saw thousands of prisoners escape after assaults on the country’s two biggest prisons.”), available at: <https://www.aljazeera.com/news/2024/3/4/thousands-of-inmates-escape-prison-amid-deepening-haiti-violence>; *see also* Reuters, “Haiti prison break leaves 12 dead as inmates go hungry” (Aug. 16, 2024) (“A prison break in the Haitian city of Saint-Marc left 12 inmates dead on Friday, Mayor Myriam Fievre said, the third such incident in Haiti in recent months amid a protracted humanitarian crisis fueled by gang violence.”), available at: <https://www.reuters.com/world/americas/haitian-inmates-escape-prison-third-recent-jailbreak-miami-herald-says-2024-08-16/>.

⁴³ U.S. Department of State, “Deportation Actions Against U.S. Legal Permanent Residents Affiliated with Haitian Foreign Terrorist Organization Viv Ansanm” (July 21, 2025), <https://www.state.gov/releases/office-of-the-spokesperson/2025/07/deportation-actions-against-u-s-legal-permanent-residents-affiliated-with-haitian-foreign-terrorist-organization-viv-ansanm/>.

⁴⁴ ICE, “ICE arrests illegal alien from Haiti connected to criminal terrorist organizations” (Sept. 25, 2025), <https://www.ice.gov/news/releases/ice-arrests-illegal-alien-haiti-connected-criminal-terrorist-organizations>.

⁴⁵ America First Policy Directive to the Secretary of State, 90 FR 8337 (Jan. 29, 2025).

⁴⁶ United Nations, “UN Security Council approves new ‘suppression force’ for Haiti amid spiraling gang violence” Sept. 30, 2025, <https://news.un.org/en/story/2025/09/1166006>.

⁴⁷ U.S. Department of State, “On the Next Steps to Restoring Security in Haiti” (Oct. 1, 2025), <https://www.state.gov/releases/2025/10/on-the-next-steps-to-restoring-security-in-haiti/>.

⁴⁸ As of November 10, 2025, approximately 18,068 of these nationals of Haiti (and aliens having

designation continue to be employment authorized until the designation ends on February 3, 2026.⁵¹ Accordingly, through this **Federal Register** notice, DHS automatically extends the validity of certain Employment Authorization Documents previously issued under the Temporary Protected Status designation of Haiti through February 3, 2026. Therefore, as proof of continued employment authorization through February 3, 2026, Temporary Protected Status beneficiaries can show their EADs that have the notation A–12 or C–19 under Category and a “Card Expires” date of February 3, 2026, August 3, 2025, August 3, 2024, June 30, 2024, February 3, 2023, December 31, 2022, October 4, 2021, January 4, 2021, January 2, 2020, July 22, 2019, January 22, 2018, or July 22, 2017.

The Secretary has considered putative reliance interests in the Haiti Temporary Protected Status designation, especially when considering whether to allow for an additional transition period akin to that allowed under certain previous Temporary Protected Status terminations. Temporary Protected Status, as the name itself makes clear, is an inherently temporary status. Temporary Protected Status designations are time-limited and must be periodically reviewed, as frequently as every six months in some cases, and Temporary Protected Status notices clearly notify aliens of the designations’ expiration dates. Further, whether to allow for an orderly transition period is left to the Secretary’s unfettered discretion. *See* INA sec. 244(b)(3), (d)(3); 8 U.S.C. 1254a(b)(3), (d)(3). The statute inherently contemplates advance notice of a termination by requiring timely publication of the Secretary’s determination and delaying the effective date of the termination by at least 60 days after publication of a **Federal Register** notice of the termination or, if later, the existing expiration date. *See* INA sec. 244(b)(3), (d)(3); 8 U.S.C. 1254a(b)(3), (d)(3).

Notice of the Termination of the Temporary Protected Status Designation of Haiti

By the authority vested in me as Secretary under INA section 244(b)(3), 8 U.S.C. 1254a(b)(3), I have reviewed, in consultation with the appropriate U.S. Government agencies, (a) conditions in Haiti; and (b) whether permitting the nationals of Haiti (and aliens having no nationality who last habitually resided in Haiti) to remain temporarily in the United States is contrary to the national

interest of the United States. Based on my review, I have determined that Haiti no longer continues to meet the conditions for Temporary Protected Status under INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).

Accordingly, I order as follows:

(1) Pursuant to INA section 244(b)(3)(B), 8 U.S.C. 1254a(b)(1)(B), and considering INA section 244(d)(3), 8 U.S.C. 1254a(d)(3), the designation of Haiti for Temporary Protected Status is terminated effective at 11:59 p.m., local time, on February 3, 2026.

(2) Information concerning the termination of Temporary Protected Status for nationals of Haiti (and aliens having no nationality who last habitually resided in Haiti) will be available at local USCIS office upon publication of this notice and through the USCIS Contact Center at 1–800–375–5283. This information will be published on the USCIS website at www.uscis.gov.

Kristi Noem,

Secretary of Homeland Security.

[FR Doc. 2025–21379 Filed 11–26–25; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[A2407–014–004–065516; #O2412–014–004–047181.1; LLNM920000]

Notice of Proposed Reinstatement of BLM New Mexico Terminated Oil and Gas Leases: NMNM 141402

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of lease reinstatement.

SUMMARY: In accordance with the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM) received a petition for reinstatement of terminated competitive oil and gas lease NMNM 141402 from Tascosa Energy Partners, LLC. The lessee timely filed a petition for reinstatement of the competitive oil and gas lease located in Eddy County, New Mexico. The lessee paid the required rentals accruing from the date of termination. No leases have been issued that affect these lands. The BLM proposes to reinstate the lease.

FOR FURTHER INFORMATION CONTACT: Julieann Serrano, Supervisory Land Law Examiner, Branch of Adjudication, Bureau of Land Management New Mexico State Office, 301 Dinosaur Trail, Santa Fe, New Mexico 87508, (505) 954–2149, jserrano@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 lessee agrees to new lease terms for rental of \$20 per acre, or fraction thereof, per year, and a royalty rate of 16.67 percent. The lessee agreed to amended stipulations. The lessee paid the required administration fee and has reimbursed the BLM for the cost of publishing this notice.

The lessee meets the requirements for reinstatement of the lease per sec. 31 (d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). The BLM is proposing to reinstate lease NMNM 141402 effective January 1, 2022, for the remainder of the primary term, subject to: the original terms and conditions of the lease; amended stipulations; increased rental of \$20 per acre; and increased royalty of 16.67 percent.

(Authority: 30 U.S.C. 188 (e)(4) and 43 CFR 3108.23.)

Joseph B. Peterson,

Acting Deputy State Director, Minerals.

[FR Doc. 2025–21454 Filed 11–26–25; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

Renewals of Information Collections Under the Paperwork Reduction Act

AGENCY: National Indian Gaming Commission.

ACTION: Notice of renewal of information collections; second request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the National Indian Gaming Commission (NIGC or Commission) is providing notice to, and seeking comments from, the general public about its submission, concurrently with the publication of this notice or soon thereafter, of the following information collection renewal requests to the Office of Management and Budget (OMB) for OMB review and approval: (i) Indian gaming management contract-related submissions, as authorized by Office of Management and Budget (OMB) Control Number 3141–0004 (expires on February 28, 2026); (ii) Indian gaming fee payments-related submissions, as

⁵¹ *See* INA 244(a)(1)(B), 8 U.S.C. 1254a(a)(1)(B); *see also* 8 CFR 244.13(b).

authorized by OMB Control Number 3141–0007 (expires on February 28, 2026); (iii) minimum internal control standards for class II gaming submission and recordkeeping requirements, as authorized by OMB Control Number 3141–0009 (expires on November 30, 2025); (iv) facility license-related submission and recordkeeping requirements, as authorized by OMB Control Number 3141–0012 (expires on December 31, 2025); and (v) minimum technical standards for class II gaming systems and equipment submission and recordkeeping requirements, as authorized by OMB Control Number 3141–0014 (expires on December 31, 2025).

DATES: The OMB has up to 60 days to approve or disapprove the information collection renewal requests but may respond after 30 days. Therefore, public comments should be submitted to OMB by December 29, 2025 to be assured of consideration.

ADDRESSES: Submit comments directly to OMB's Office of Information and Regulatory Affairs, Attn: Policy Analyst/Desk Officer for the National Indian Gaming Commission. Comments can also be emailed to OIRA_Submission@omb.eop.gov; include reference to "NIGC PRA Renewals" in the subject line.

FOR FURTHER INFORMATION CONTACT: For further information, including copies of the proposed information collection requests and supporting documentation, contact Tim Osumi at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers). You may also review these information collection requests by going to <http://www.reginfo.gov> (Information Collection Review, Currently Under Review, Agency: National Indian Gaming Commission).

SUPPLEMENTARY INFORMATION:

I. Abstract

The gathering of this information is in keeping with the purposes of the Indian Gaming Regulatory Act of 1988 (IGRA or the Act), Public Law 100–497, 25 U.S.C. 2701, *et seq.*, which include: providing a statutory basis for the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments; ensuring that the Indian tribe is the primary beneficiary of the gaming operation; and declaring that the establishment of independent federal regulatory authority for gaming on Indian lands, the establishment of federal standards for gaming on Indian lands, and the establishment of the Commission are necessary to meet congressional

concerns regarding gaming and to protect such gaming as a means of generating tribal revenue. 25 U.S.C. 2702. The Act established the Commission and laid out a comprehensive framework for the regulation of gaming on Indian lands.

II. Data

Title: Management Contract Provisions.

OMB Control Number: 3141–0004.

Brief Description of Collection: The Indian Gaming Regulatory Act (IGRA or the Act), Public Law 100–497, 25 U.S.C. 2701, *et seq.*, established the National Indian Gaming Commission (NIGC or Commission) and laid out a comprehensive framework for the regulation of gaming on Indian lands. Amongst other actions necessary to carry out the Commission's statutory duties, the Act requires the NIGC Chair to review and approve all management contracts for the operation and management of class II and/or class III gaming activities, and to conduct background investigations of persons with direct or indirect financial interests in, and management responsibility for, management contracts. 25 U.S.C. 2710, 2711. The Commission is authorized to "promulgate such regulations and guidelines as it deems appropriate to implement" IGRA. 25 U.S.C.

2706(b)(10). The Commission has promulgated parts 533, 535, and 537 of title 25, Code of Federal Regulations, to implement these statutory requirements.

Section 533.2 requires a tribe or management contractor to submit a management contract for review within 60 days of execution, and to submit all the items specified in § 533.3. Section 535.1 requires a tribe to submit an amendment to a management contract within 30 days of execution, and to submit all the items specified in § 535.1(c). Section 535.2 requires a tribe or a management contractor, upon execution, to submit the assignment by a management contractor of its rights under a previously approved management contract. Section 537.1 requires a management contractor to submit all of the items specified in § 537.1(b),(c) in order for the Commission to conduct background investigations on: each person with management responsibility for a management contract; each person who is a director of a corporation that is a party to a management contract; the ten persons who have the greatest direct or indirect financial interest in a management contract; any entity with a financial interest in a management contract; and any other person with a direct or indirect financial interest in a

management contract, as otherwise designated by the Commission. This collection is mandatory, and the benefit to the respondents is the approval of Indian gaming management contracts, and any amendments thereto.

Respondents: Tribal governing bodies and management contractors.

Estimated Number of Respondents: 33.

Estimated Annual Responses: 51 (submissions of contracts, contract amendments, contract assignments, and background investigation material).

Estimated Time per Response: Depending on the type of submission, the range of time can vary from 1 burden hours to 16 burden hours for one item.

Frequency of Response: Usually no more than once per year.

Estimated Total Annual Burden

Hours on Respondents: 620.

Estimated Total Non-hour Cost Burden: \$ 125,271.

Title: Fees.

OMB Control Number: 3141–0007.

Brief Description of Collection: The Indian Gaming Regulatory Act (IGRA or the Act), 25 U.S.C. 2701, *et seq.*, laid out a comprehensive framework for the regulation of gaming on Indian lands. Amongst other actions necessary to carry out the Commission's statutory duties, the Act requires Indian tribes that conduct a class II and/or class III gaming activity to pay annual fees to the Commission based on the assessable gross revenues of each gaming operation using rates established by the Commission. 25 U.S.C. 2717. The Commission is authorized to "promulgate such regulations and guidelines as it deems appropriate to implement" IGRA. 25 U.S.C. 2706(b)(10). The Commission has promulgated part 514 of title 25, Code of Federal Regulations, to implement these statutory requirements.

Section 514.6 requires a tribe to submit, along with its fee payments, quarterly fee statements (worksheets) showing its assessable gross revenues for the previous fiscal year to support the computation of fees paid by each gaming operation. Section 514.7 requires a tribe to submit a notice within 30 days after a gaming operation changes its fiscal year. Section 514.15 allows a tribe to submit fingerprint cards to the Commission for processing by the Federal Bureau of Investigation (FBI), along with a fee to cover the NIGC's and FBI's cost to process the fingerprint cards on behalf of the tribes. Part of this collection is mandatory, and the other part is voluntary. The required submission of the fee worksheets allows the Commission to both set and adjust

fee rates, and to support the computation of fees paid by each gaming operation. In addition, the voluntary submission of fingerprint cards allows a tribe to conduct statutorily mandated background investigations on applicants for key employee and primary management official positions.

Respondents: Indian gaming operations.

Estimated Number of Respondents: 708.

Estimated Annual Responses: 52,451.

Estimated Time per Response: Depending on the type of submission, the range of time can vary from 0.5 burden hours to 3 burden hours for one item.

Frequency of Response: Quarterly (for fee worksheets); varies (for fingerprint cards and fiscal year change notices).

Estimated Total Annual Burden on Respondents: 31,098.

Estimated Total Non-hour Cost Burden: \$ 1,648,255.

Title: Minimum Internal Control Standards for Class II Gaming.

OMB Control Number: 3141–0009.

Brief Description of Collection: The Indian Gaming Regulatory Act (IGRA or the Act), 25 U.S.C. 2701, *et seq.*, laid out a comprehensive framework for the regulation of gaming on Indian lands. Amongst other actions necessary to carry out the Commission's statutory duties, the Act directs the Commission to monitor class II gaming conducted on Indian lands on a continuing basis in order to adequately shield Indian gaming from organized crime and other corrupting influences, to ensure that the Indian tribe is the primary beneficiary of the gaming operation, and to assure that gaming is conducted fairly and honestly by both the operator and players. 25 U.S.C. 2702(2), 2706(b)(1). The Commission is also authorized to "promulgate such regulations and guidelines as it deems appropriate to implement" IGRA. 25 U.S.C. 2706(b)(10). The Commission has promulgated part 543 of title 25, Code of Federal Regulations, to aid it in monitoring class II gaming on a continuing basis.

Section 543.3 requires a tribal gaming regulatory authority (TGRA) to submit to the Commission a notice requesting an extension to the deadline (by an additional six months) to achieve compliance with the requirements of the new tier after a gaming operation has moved from one tier to another. Section 543.5 requires a TGRA to submit a detailed report after the TGRA has approved an alternate standard to any of the NIGC's minimum internal control standards, and the report must contain

all the items specified in § 543.5(a)(2). Section 543.23(c) requires a tribe to maintain internal audit reports and to make such reports available to the Commission upon request. Section 543.23(d) requires a tribe to submit two copies of the agreed-upon procedures (AUP) report within 120 days of the gaming operation's fiscal year end. This collection is mandatory and allows the NIGC to confirm tribal compliance with the minimum internal control standards.

Respondents: Tribal governing bodies.

Estimated Number of Respondents: 412.

Estimated Annual Responses: 840.

Estimated Time per Response:

Depending on the tier level of the gaming facility, the range of time can vary from 1 burden hour to 7 burden hours for one AUP audit report.

Frequency of Response: Annually.

Estimated Total Annual Hourly Burden to Respondents: 252.

Estimated Total Non-hour Cost Burden: \$ 3,866,060.

Title: Facility License Notifications and Submissions.

OMB Control Number: 3141–0012.

Brief Description of Collection: The Indian Gaming Regulatory Act (IGRA or the Act), 25 U.S.C. 2701, *et seq.*, laid out a comprehensive framework for the regulation of gaming on Indian lands. Amongst other actions necessary to carry out the Commission's statutory duties, the Act requires Indian tribes that conduct class II and/or class III gaming to issue "a separate license . . . for each place, facility, or location on Indian lands at which class II [and class III] gaming is conducted," 25 U.S.C. 2710(b)(1), (d)(1), and to ensure that "the construction and maintenance of the gaming facilities, and the operation of that gaming is conducted in a manner which adequately protects the environment and public health and safety." 25 U.S.C. 2710(b)(2)(E). The Commission is authorized to "promulgate such regulations and guidelines as it deems appropriate to implement" IGRA. 25 U.S.C. 2706(b)(10). The Commission has promulgated part 559 of title 25, Code of Federal Regulations, to implement these requirements.

Section 559.2 requires a tribe to submit a notice (that a facility license is under consideration for issuance) at least 120 days before opening any new facility on Indian lands where class II and/or class III gaming will occur, with the notice containing all the items specified in § 559.2(b). Section 559.3 requires a tribe to submit a copy of each newly issued or renewed facility license within 30 days of issuance. Section

559.4 requires a tribe to submit an attestation certifying that by issuing the facility license, the tribe has determined that the construction, maintenance, and operation of that gaming facility is conducted in a manner that adequately protects the environment and the public health and safety. Section 559.5 requires a tribe to submit a notice within 30 days if a facility license is terminated or expires or if a gaming operation closes or reopens. Section 559.6 requires a tribe to maintain and provide applicable and available Indian lands or environmental and public health and safety documentation, if requested by the NIGC. This collection is mandatory and enables the Commission to perform its statutory duty by ensuring that tribal gaming facilities on Indian lands are properly licensed by the tribes.

Respondents: Indian tribal gaming operations.

Estimated Number of Respondents: 336.

Estimated Annual Responses: 679.

Estimated Time per Response:

Depending on the type of submission, the range of time can vary from 1 burden hours to 3 burden hours for one item.

Frequency of Response: Varies.

Estimated Total Annual Hourly Burden to Respondents: 1,429.

Estimated Total Non-hour Cost Burden: \$ 0.

Title: Minimum Technical Standards for Class II Gaming Systems and Equipment.

OMB Control Number: 3141–0014.

Brief Description of Collection: The Indian Gaming Regulatory Act (IGRA or the Act), 25 U.S.C. 2701, *et seq.*, laid out a comprehensive framework for the regulation of gaming on Indian lands. Amongst other actions necessary to carry out the Commission's statutory duties, the Act directs the Commission to monitor class II gaming conducted on Indian lands on a continuing basis in order to adequately shield Indian gaming from organized crime and other corrupting influences, to ensure that the Indian tribe is the primary beneficiary of the gaming operation, and to assure that gaming is conducted fairly and honestly by both the operator and players. 25 U.S.C. 2702(2), 2706(b)(1). The Act allows Indian tribes to use "electronic, computer, or other technologic aids" to conduct class II gaming activities. 25 U.S.C. 2703(7)(A). The Commission is authorized to "promulgate such regulations and guidelines as it deems appropriate to implement" IGRA. 25 U.S.C. 2706(b)(10). The Commission has promulgated part 547 of title 25, Code of Federal Regulations, to aid it in monitoring class II gaming facilities that

are using electronic, computer, or other technologic aids to conduct class II gaming.

Section 547.5(a)(2) requires that, for any grandfathered class II gaming system made available for use at any tribal gaming operation, the tribal gaming regulatory authority (TGRA): must retain copies of the gaming system's testing laboratory report, the TGRA's compliance certificate, and the TGRA's approval of its use; and must maintain records identifying these grandfathered class II gaming systems and their components. Section 547.5(b)(2) requires that, for any class II gaming system generally, the TGRA must retain a copy of the system's testing laboratory report and maintain records identifying the system and its components. As long as a class II gaming system is available to the public for play, section 547.5(c)(3) requires a TGRA to maintain records of any modification to such gaming system and a copy of its testing laboratory report. Section 547.5(d)(3) requires a TGRA to maintain records of approved emergency hardware and software modifications to a class II gaming system (and a copy of the testing laboratory report) so long as the gaming system remains available to the public for play and must make the records available to the Commission upon request. Section 547.5(f) requires a TGRA to maintain records of its following determinations: (i) regarding a testing laboratory's (that is owned or operated or affiliated with a tribe) independence from the manufacturer and gaming operator for whom it is providing the testing, evaluating, and reporting functions; (ii) regarding a testing laboratory's suitability determination based upon standards no less stringent than those set out in 25 CFR 533.6(b)(1)(ii) through (v) and based upon no less information than that required by 25 CFR 537.1; and/or (iii) the TGRA's acceptance of a testing laboratory's suitability determination made by any other gaming regulatory authority in the United States. The TGRA must maintain said records for a minimum of three years and must make the records available to the Commission upon request. Section 547.17 requires a TGRA to submit a detailed report for each enumerated standard for which the TGRA approves an alternate standard, and the report must include: (i) an explanation of how the alternate standard achieves a level of security and integrity sufficient to accomplish the purpose of the standard it is to replace; and (ii) the alternate standard as approved and the record on which the

approval is based. This collection is mandatory and allows the NIGC to confirm tribal compliance with NIGC regulations on "electronic, computer, or other technologic aids" to conduct class II gaming activities.

Respondents: Tribal governing bodies.

Estimated Number of Respondents: 811.

Estimated Annual Responses: 811.

Estimated Time per Response:

Depending on the type of submission, the range of time can vary from 1 burden hour to 17 burden hours for one item.

Frequency of Response: Annually.

Estimated Total Annual Hourly

Burden to Respondents: 8,897.

Estimated Total Non-hour Cost

Burden: \$0.

Dated: November 25, 2025.

Sharon M. Avery,
Chairwoman (Acting).

[FR Doc. 2025–21500 Filed 11–26–25; 8:45 am]

BILLING CODE 7565–01–P

INTERNATIONAL TRADE COMMISSION

Appointment of Individuals To Serve as Members of the Performance Review Board

AGENCY: United States International Trade Commission.

ACTION: Appointment of Individuals to Serve as Members of Performance Review Board.

DATES: Applicable Date: November 25, 2025.

FOR FURTHER INFORMATION CONTACT: Eric Mozie, Director of Human Resources, or Ronald Johnson, Deputy Director of Human Resources, U.S. International Trade Commission, (202) 205–2651.

SUPPLEMENTARY INFORMATION: The Chair of the U.S. International Trade Commission has appointed the following individuals to serve on the Commission's Performance Review Board (PRB):

Chair of the PRB: Commissioner David Johanson

Vice Chair of the PRB: Commissioner Jason Kearns

Member—Fay Johnson

Member—Nannette Christ

Member—Catherine DeFilippo

Member—Silvia Galluch

Member—Katie Higginbotham

Member—Margaret Macdonald

Member—William Powers

Member—Keith Vaughn

Member—Jeremy Wise

This notice is published in the **Federal Register** pursuant to the

requirement of 5 U.S.C. 4314(c)(4). Hearing impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 205–1810.

By order of the Chairman.

Issued: November 25, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–21496 Filed 11–26–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1462]

Certain Liquid Crystal Display Devices, Components Thereof, and Products Containing the Same; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 29, 2025, under section 337 of the Tariff Act of 1930, as amended, on behalf of BH Innovations LLC of New York, New York. The complaint was amended on September 19, 2025, to add Longitude Licensing Limited of Ireland, and 138 East LCD Advancements Ltd. of Ireland as complainants. A supplement to the complaint was filed on September 25, 2025. The complaint, as amended and supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain liquid crystal display devices, components thereof, and products containing the same by reason of the infringement of certain claims of U.S. Patent No. 7,705,948 ("the '948 patent") and U.S. Patent No. 7,570,334 ("the '334 patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD

terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Susan Orndoff, The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–2560 or (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2025).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 24, 2025, *ordered that—*

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claim 1 of the '948 patent and claim 1 of the '334 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "LCD devices composed of two glass substrates sandwiching a layer of liquid crystal pixels and the associated circuitry for controlling the amount of light passing through those pixels, components thereof, and products containing same";

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) *The complainants are:*

BH Innovations LLC, 401 East 89th Street, #18B, New York, NY 10128.
Longitude Licensing Limited, Plaza 255, Blanchardstown Corporate Park 2, Dublin 15, D15 YH6H, Ireland.

138 East LCD Advancements Ltd., Plaza 255, Blanchardstown Corporate Park 2, Dublin 15, D15 YH6H, Ireland.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

HKC Corporation Ltd., 5F and 7F, Factory Building 1, HKC Industrial Park, 1 Gongye 2nd Road, Baoan District, Shenzhen City, Guangdong Province, 518108, China.

Chongqing HKC Optoelectronics, Technology Co., Ltd., No. 1 Shijing Road, Jieshi, Banan District, Chongqing, 401320, China.

HKC Overseas Ltd., Unit 8 28/F W50, 50 Wong Chuk Hang Road, Hong Kong.

HiSense Co., Ltd., 22F, Hisense Tower, 17 Donghai Xi Road, Qingdao, 266071, China.

HiSense International Co., Ltd., 22F, Hisense Tower, 17 Donghai Xi Road, Qingdao, 266071, China.

HiSense Visual Technology Co. Ltd. 218 Qianwangang Road, Qingdao Economic & Technological, Development Zone, Qingdao, 266555, China.

HiSense US Corporation., 7310 McGinnis Ferry Rd., Suwanee, GA 30024.

VIZIO Holding Corp., 39 Tesla, Irvine, California 92618.

TCL Electronics Holdings Ltd., 5/F, Building 22E, 22 Science Park East Avenue, Hong Kong Science Park, Shatin, New Territories, Hong Kong.

Shenzhen TCL New Technology Co. Ltd., TCL Electronics Building, TCL International E City, 1001 Zhongshanyuan Road, Nanshan District, Shenzhen, Guangdong, Province, 518052, China.

TCL King Electrical Appliances Co. Ltd., No.78, Huifeng 4th Road, Huihuan Town, Huicheng District, Huizhou, Guangdong, Province, 516006, China.

TTE Technology Inc., 189 Technology Drive, Irvine, California 92618.

TCL Technology Group Corp., TCL Tech Building, 17 Huifeng Third Road, Zhongkai Hi-Tech Development District, Huizhou City, Guangdong Province, 516006, China.

TCL Moka International Ltd., TCL Tower, 8 Tai Chung Road, Tsuenwan, New Territories, Hong Kong.

TCL Overseas Marketing Ltd., 22 Science Park East Avenue, Hong Kong Science Park, Shatin, New Territories, Hong Kong.

TCL Industries Holdings Co., Ltd., TCL Electronics Tower, Building D4, TCL International E City, 1001 Zhongshanyuan Road, Nanshan

District, Shenzhen, Guangdong, Province, 518052, China.

TCL Smart Device (Vietnam) Co. Ltd., No. 26 VSIP II–A, Road No. 32, Viet Nam—Singapore II–A Industrial Park, Tan Binh Town, North Tan Uyen District, Binh Duong Province, Vietnam.

LG Electronics, Inc., LG Twin Towers, 20 Yoido-dong, Youngdungpo-gu, Seoul, Republic of Korea.

LG Electronics USA, Inc., 111 Sylvan Avenue, Englewood Cliffs, New Jersey 07632.

Westinghouse Electric Corporation, 4000 Town Center Blvd., Suite 210, Canonsburg, Pennsylvania 15317.

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 24, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–21350 Filed 11–26–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation. No. 337-TA-1463]

Certain Microcurrent Facial Toning Devices and Systems Thereof; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 4, 2025, under section 337 of the Tariff Act of 1930, as amended, on behalf of ZIIP, Inc. of Pleasant Hill, California and The Beauty Tech Group Ltd. of the United Kingdom. A supplement to the complaint was filed on September 15, 2025. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain microcurrent facial toning devices and systems thereof by reason of the infringement of certain claims of U.S. Patent No. 10,967,180 (“the ‘180 patent”) and U.S. Patent No. 12,042,652 (“the ‘652 patent”). The complaint, as supplemented, further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT: Susan Orndoff, The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205-1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is

contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10 (2025).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 24, 2025, Ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–4, 6, 7, 9, 11, and 12 of the ‘180 patent and claims 1–6, 8, 10, 12, 14, 15, and 18–20 of the ‘652 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “handheld facial toning devices and accessories for such devices that are used in conjunction with a mobile application”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:
ZIIP, Inc., 2495 Estand Way, Pleasant Hill, CA 94523.
The Beauty Tech Group Ltd.,
Glasshouse, Block 1s1 Congleton Road, Nether Alderley, Macclesfield, Cheshire, United Kingdom, SK10 4ZE.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served:
The Carol Cole Co. d/b/a NuFACE, 1325 Sycamore Avenue, Suite A, Vista, CA 92081.

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the

Commission’s Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 24, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-21353 Filed 11-26-25; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-624-625 and 731-TA-1450-1451 (Review)]

Quartz Surface Products From India and Turkey; Revised Schedule for the Subject Proceeding

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: November 21, 2025.

FOR FURTHER INFORMATION CONTACT: Caitlyn Costello (202-205-2058), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for

this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: Effective August 4, 2025, the Commission established a schedule for the conduct of the subject proceeding (90 FR 45245, September 19, 2025). Due to the lapse in appropriations and ensuing cessation of Commission operations, the Commission is revising its schedule as follows: comments are due on November 18, 2025.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: November 24, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–21408 Filed 11–26–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–451 and 731–TA–1126 (Third Review)]

Lightweight Thermal Paper From China; Revised Schedule for the Subject Proceeding

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: November 21, 2025.

FOR FURTHER INFORMATION CONTACT:

Alexis Yim (202–708–1446), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: Effective September 5, 2025, the Commission established a schedule for the conduct of the subject proceeding (90 FR 45809, September 23, 2025). Due to the lapse in appropriations and ensuing cessation of Commission operations, the Commission is revising its schedule as follows: the staff report will be placed in the nonpublic record on December 3, 2025; comments are due on December 9, 2025.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: November 25, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–21432 Filed 11–26–25; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1568P]

Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2026

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2026 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before December 15, 2025. Commenters should be aware that the electronic Federal

Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the **Federal Register** a final order establishing the 2026 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. 1568P” on all correspondence, including any attachments. DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment.

Please be aware that submitted comments are not instantaneously available for public view on [Regulations.gov](https://www.regulations.gov). If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Heather E. Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

Legal Authority

Section 306 of the Controlled Substances Act (21 U.S.C. 826) requires the Attorney General to establish production quotas for each basic class of controlled substances listed in schedules I and II, and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The

Attorney General has delegated this function to the Administrator of DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2026 Aggregate Production Quotas and Assessment of Annual Needs

The proposed 2026 aggregate production quotas (APQ) and assessment of annual needs (AAN) represent those quantities of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2026 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

Aggregate Production Quotas

In determining the proposed 2026 APQ, the Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1303.11, including the following seven factors:

- (1) Total net disposal of the class by all manufacturers during the current and two preceding years;
- (2) Trends in the national rate of net disposal of the class;
- (3) Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;
- (4) Projected demand for such class as indicated by procurement quotas requested pursuant to [21 CFR] 1303.12;
- (5) The extent of any diversion of the controlled substance in the class;
- (6) Relevant information obtained from the Department of Health and Human Services (HHS), including from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS), and relevant information obtained from the states; and
- (7) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions

to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 CFR 1303.11(b).

DEA formally solicited data from the HHS agency FDA in March 2025 and from the states in April 2025, pursuant to 21 CFR part 1303. DEA did not solicit input from CMS for reasons discussed in previous notices.¹ While DEA is requesting data from CDC, this request has been inadvertently delayed. Data received from the CDC that is relevant to the 2026 APQs will be considered in finalizing and/or adjusting the APQs. DEA requested information on trends in the legitimate use of select schedule I and II controlled substances from FDA. DEA's request for information from the states was made directly to the Prescription Drug Monitoring Program (PDMP) Administrators in each state as well as through the National Association of State Controlled Substances Authorities (NASCSA).

Assessment of Annual Needs

In similar fashion, in determining the proposed 2026 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, the Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1315.11, including the following five factors:

- (1) Total net disposal of the chemical by all manufacturers and importers during the current and two preceding years;
- (2) Trends in the national rate of net disposal of each chemical;
- (3) Total actual (or estimated) inventories of the chemical and of all substances manufactured from the chemical, and trends in inventory accumulation;
- (4) Projected demand for each chemical as indicated by procurement and import quotas requested pursuant to [21 CFR] 1315.32; and
- (5) Other factors affecting medical, scientific, research, and industrial needs in the United States, lawful export requirements, and the establishment and maintenance of reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemicals or the substances

¹ Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020, 85 FR 54414 (Sept. 1, 2020) and Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021, 85 FR 54407 (Sept. 1, 2020).

manufactured from them, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 CFR 1315.11(b).

In determining the proposed 2026 AAN, DEA used the calculation methodology previously described in the 2010 and 2011 assessments of annual needs (74 FR 60294 (Nov. 20, 2009) and 75 FR 79407 (Dec. 20, 2010), respectively).

Estimates of Medical Need for Schedule II Opioids and Stimulants

In accordance with 21 CFR part 1303, 21 U.S.C. 826, and 42 U.S.C. 242, HHS continues to provide DEA with estimates of the quantities of select schedule I and II controlled substances and three list I chemicals that will be required to meet the legitimate medical needs of the United States for a given calendar year. The responsibility to provide these estimates of legitimate domestic medical needs resides with FDA. FDA provides DEA with predicted estimates of domestic medical usage for selected controlled substances based on information available to them at a specific point in time in order to meet statutory requirements. In July 2025, FDA provided DEA with the predicted estimates of domestic medical usage for selected controlled substances for 2026, which DEA considered in developing the proposed 2026 APQ.

DEA observed an average of a 10.56 percent decrease in the medical usage of the schedule II opioids codeine, morphine, fentanyl, hydrocodone, hydromorphone, oxycodone and oxymorphone for the United States in 2024 compared to 2023. DEA projects that the medical usage of these controlled substances will continue to decline in 2026 based on a review of domestic usage data from IQVIA. DEA also considered the potential for diversion of these opioids, as required by 21 CFR 1303.11(b)(5). Additionally, DEA has observed a significant decline in requests for product development quotas to support manufacturing towards FDA approval of drug products containing oxycodone. Accordingly, the APQs for codeine (for sale), morphine (for sale), fentanyl, hydrocodone (for sale), hydromorphone, oxycodone (for sale), and oxymorphone (for sale) are being proposed as reductions from their 2025 established APQ value.

DEA is proposing a slight increase to the remifentanyl APQ from the 2025 established APQ. Remifentanyl is a

schedule II synthetic opioid analgesic that is primarily administered intravenously to manage pain during and after surgical procedures. DEA reviewed the most recently available domestic usage data from IQVIA and export data from DEA's internal database. Domestic medical usage of remifentanyl has been increasing every year since 2020. Additionally, exports of this active pharmaceutical ingredient (API) have also increased from 2022 to 2024. Thus, DEA is proposing a higher APQ of remifentanyl for 2026 than DEA initially established for 2025, to support increasing domestic medical use and export requirements.

DEA is also proposing an increase to the noroxymorphone (for sale) APQ from the 2025 established APQ to accommodate a manufacturer's request to manufacture reference standards, and to evaluate and identify unknown impurities in the manufacturing process. This additional APQ will also accommodate the manufacturer's need to conduct additional product development manufacturing activities to optimize the synthesis of noroxymorphone (for sale).

DEA observed an average of a 6.74 percent increase in domestic medical use of the schedule II stimulants amphetamine, methylphenidate (including dexmethylphenidate), and lisdexamfetamine in 2024 compared to 2023. Medications containing one of these controlled substances are commonly prescribed to treat patients with attention deficit hyperactivity disorder (ADHD). In 2025, dosage form manufacturers reported shortages of specific ADHD medications containing amphetamine, lisdexamfetamine, and methylphenidate to FDA. The stated reasons for these specific shortages include increases in product demand, supply chain issues, manufacturing and quality issues, lack of active ingredients, and business decisions of manufacturers. DEA considered drug shortage concerns when determining the proposed APQs for these substances.

In proposing the APQs for d-amphetamine (for sale), d,l-amphetamine, and methylphenidate, DEA considered manufacturers' reported inventories for amphetamine and methylphenidate-based products and determined that the 2026 APQs should be proposed at their 2025 adjusted APQ levels. DEA believes the inventories, when combined with the proposed 2026 APQs, will be sufficient to support the estimated increases in domestic medical use and export requirements of amphetamine and methylphenidate-based products.

With respect to lisdexamfetamine, DEA is proposing an increase from the 2025 established lisdexamfetamine APQ to address increased prescribing, export requirements, and to ensure sufficient inventory for domestic manufacturers of FDA-approved lisdexamfetamine drug products. DEA recognizes that global consumption is increasing with almost 30 countries approving the use of lisdexamfetamine drug products to treat specific medical conditions. DEA reviewed the most recently available domestic usage data from IQVIA and export data from DEA's internal database and Multi International Data Analysis System (MIDAS). Extrapolation of the data predicts domestic use will increase 8.94 percent and export requirements will increase 14.85 percent in 2026. This double-digit increase in export requirements follows from the brand name product, Vyvanse, successfully being approved to treat patients suffering from attention-deficit/hyperactivity disorder (ADHD) in 29 countries in addition to the United States. Furthermore, Vyvanse is expected to launch in additional foreign countries between 2025 and 2027. Additional U.S. dosage form manufacturers have also begun exporting lisdexamfetamine finished dosage-form products according to the data extracted from DEA's internal databases. Reviewing internal databases, DEA determined that bulk manufacturers started 2025 with less than the 40% inventory allowance permitted by 21 CFR 1303.24. Increasing the lisdexamfetamine APQ in 2026 would allow the manufacturers to maintain the 40% inventory allowance permitted by 21 CFR 1303.24 while meeting the estimated increasing legitimate domestic and global demands. Thus, DEA is proposing a higher lisdexamfetamine APQ for 2026 than DEA initially established for 2025.

DEA is also proposing a corresponding increase to the APQ of d-amphetamine (for conversion) over the 2025 level. The synthesis route to manufacture lisdexamfetamine requires the manufacturing of a controlled substance intermediate, d-amphetamine (for conversion). In most synthesis pathways, lisdexamfetamine cannot be manufactured without synthesizing d-amphetamine (for conversion) as an intermediate step, thus the APQ of d-amphetamine (for conversion) is proposed to increase commensurately to the lisdexamfetamine APQ increase.

DEA Projected Trends for Certain Schedule I Controlled Substances

DEA is proposing a higher APQ than the 2025 established APQs for the

following schedule I controlled substances: 3,4-methylenedioxy-N-methylcathinone, 5-methoxy-N-N-dimethyltryptamine, psilocybin and psilocyn to support manufacturing activities related to the increased level of research and clinical trials. Research and clinical trials are being conducted with these substances for potential treatment of conditions such as post-traumatic stress disorder (PTSD) and depression.

Information Received for Consideration of the Remaining Factors

For the factors listed in 21 CFR 1303.11(b)(3) and (4), DEA registered manufacturers of controlled substances in schedules I and II provide information such as inventory, distribution, manufacturing, sales forecasts and quota requests to DEA database systems. See 21 CFR 1303.12, 1303.22, and part 1304.

The regulation at 21 CFR 1303.11(b)(5) requires DEA to consider the extent of diversion of controlled substances.² Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than legitimate medical purposes. In order to consider the extent of diversion, DEA analyzed reports of diversion of controlled substances from 2024 submitted to its Theft Loss Report database. This database is comprised of DEA registrant reports documenting diversion from the legitimate distribution chain, including employee thefts, break-ins, armed robberies, and material lost in transit. The data was categorized by basic drug class, and the amount of active pharmaceutical ingredient (API) in the dosage form was delineated with an appropriate metric for use in proposing aggregate production quota values (i.e., weight).

Estimates of Diversion of Covered Controlled Substances

In establishing any quota . . . , or any procurement quota established by [DEA] by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a “covered controlled substance”), [DEA] shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

21 U.S.C. 826(i)(1)(A).

In estimating diversion under that provision, DEA:

(i) shall consider information . . . , in consultation with the Secretary of Health and Human Services, [it] determines reliable on rates of overdose deaths and abuse and

² The estimates of diversion for five “covered controlled substances” as required by 21 U.S.C. 826(i) are discussed later in the document.

overall public health impact related to the covered controlled substance in the United States; and

(ii) may take into consideration whatever other sources of information [it] determines reliable.

21 U.S.C. 826(i)(1)(B).

The statute further mandates that DEA “make appropriate quota reductions, as determined by [DEA], from the quota [it] would have otherwise established had such diversion not been considered.”³

In estimating the amount of diversion of each covered controlled substance that occurs in the United States, DEA considered information from state PDMP Administrators and from legitimate distribution chain participants.

Consideration of Information From Certain State PDMPs and From National Sales Data

Pursuant to 21 CFR 1303.11(b)(6), DEA requested state PDMP data for the purpose of establishing its APQ. DEA believes state PDMPs to be an essential, reliable source of information for use in effectively estimating diversion of the five covered controlled substances. In April 2025, DEA sent a letter to NASCSA requesting its assistance in obtaining aggregated PDMP data for the five covered controlled substances from each state covering the years 2022–2024. The letter indicated that DEA was specifically interested in an analysis of prescription data from each state’s PDMP that would assist DEA in estimating diversion and setting appropriate quotas in compliance with 21 U.S.C. 826(i). In its request, DEA provided specific questions, discussed in detail below, based on common indicia of potential diversion known as “red flags” by physicians, pharmacists, manufacturers, distributors, and federal and state regulatory and law enforcement agencies.⁴ DEA investigators and administrative prosecutors also rely on Agency case law in which these red flags of diversion have been upheld as indicia of potential diversion.⁵ Certain state regulations now include red flag circumstances as potential indicators of illegitimate prescriptions, and thus of potential abuse and diversion of controlled

³ 21 U.S.C. 826(i)(1)(C).

⁴ National Association of Boards of Pharmacy (NABP) coalition consensus document “Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances” (2015). www.nabp.pharmacy/resources/reports.

⁵ The Medicine Shoppe, 79 FR 59504, 59507, 59512–13 (Oct. 2, 2014); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (Oct. 12, 2012).

substances.⁶ See, e.g., The Pharmacy Place Order, 86 FR 21008, 21012 (Apr. 21, 2021) (citing 22 Tex. Admin. Code 291.29(c)(4), specifying the geographical distance between the practitioner and the patient or between the pharmacy and the patient as a red flag).

DEA requested responses from state PDMP Administrators by June 15, 2025. NASCSA disseminated DEA’s request to its PDMP Administrators and provided them with a report tool to ensure that responses to DEA’s questions were extracted consistently across all responsive states. Thirty-one states and three territories provided DEA with summarized PDMP data as of July 2025, utilizing the standardized report developed by NASCSA.⁷ See Table 1a below.

TABLE 1a—STATES/TERRITORIES THAT RESPONDED TO DEA’S DATA REQUEST

State/territory
1. Alabama.
2. Alaska.
3. Arizona.
4. Arkansas.
5. Commonwealth of Northern Mariana Islands.
6. Connecticut.
7. Delaware.
8. District of Columbia.
9. Idaho.
10. Indiana.
11. Iowa.
12. Kansas.
13. Kentucky.
14. Louisiana.
15. Maine.
16. Maryland.
17. Michigan.
18. Minnesota.
19. Mississippi.
20. Missouri.
21. Montana.
22. Nevada.
23. New Jersey.
24. New Mexico.
25. North Carolina.
26. Ohio.
27. Oregon.
28. Pennsylvania.
29. Puerto Rico.
30. South Carolina.
31. South Dakota.
32. Texas.
33. Utah.
34. Virginia.

Pharmacies are required by state law to enter controlled substance dispensing data into the state’s PDMP database, including the prescriber’s name,

⁶ The mere indicia of red flags alone is not proof of violation of 21 U.S.C. 824 or any other provision of the CSA. This rule discusses only their use by DEA as an analytical tool to estimate diversion.

⁷ NASCSA formatted DEA’s request into an analytics model developed by one of its associates, Appriss Inc.

registered address and DEA number; prescription information (such as drug name); dispensing date; dosage dispensed; pharmacy registered address; and patient name and address. DEA considers PDMP data to be an accurate representation of dispensing activities in states. DEA received data for the following red-flag metrics:

- The total number of patients who saw three or more prescribers in a 90-day period and were dispensed an opioid following each visit. For this metric, DEA requested and was provided the number of prescriptions for the five covered controlled substances dispensed to these patients, as a percentage of the total prescriptions dispensed for that particular covered controlled substance, as well as the corresponding quantity of the covered controlled substance dispensed. This metric (patients being prescribed covered controlled substances from three or more prescribers in a 90-day period) is used to identify potential doctor shopping, a common technique to obtain a high number of controlled substances, which may lead to abuse or diversion of controlled substances. DEA has long considered doctor shopping to be an indicator of potential diversion.⁸

- The number of patients that were dispensed prescriptions for each of the five covered controlled substances that exceeded 240 morphine milligram equivalents (MME) daily. States provided the raw number of such prescriptions dispensed, the number of prescriptions as a percentage of the total covered controlled substance prescriptions dispensed, and the corresponding quantity of the covered controlled substance dispensed. DEA believes that accounting for quantities in excess of 240 MME daily allows for consideration of oncology patients with legitimate medical needs for covered controlled substance prescriptions with high MME. Higher dosages place individuals at higher risk of overdose and death. Prescriptions involving dosages exceeding 240 MME daily may indicate diversion, such as illegal distribution of controlled substances or prescribing outside the usual course of professional practice.

- The number of patients that paid cash for covered controlled substance prescriptions, without submitting for insurance reimbursement.⁹ States also provided the number of prescriptions paid entirely with cash as a percentage

of the total prescriptions for the five covered controlled substances dispensed, as well as the corresponding quantity of the covered controlled substances dispensed. When investigating potential diversion, cash payments are one element considered in identifying prescriptions filled for nonmedical purposes. Unusually high percentages of cash payments made to a prescriber or pharmacy for controlled substances may indicate diversion.¹⁰

DEA received PDMP data from the states in a standardized format that allowed DEA to aggregate the data. The PDMP data sample represents a population of approximately 112.35 million people, which is approximately 34 percent of the U.S. population. DEA believes this sample is sufficient to derive a reasonable nationwide estimate.

While PDMP data is useful in estimating diversion, it is not conclusive. Further investigation would be required before concluding that any of the subject prescriptions were actually diverted. DEA continues to evaluate its methodologies in estimating diversion in an effort to set quotas more efficiently. State participation is crucial to accurate data analysis, and DEA anticipates working closely with states, as well as other federal and state entities, in future quota determinations.

To calculate a national diversion estimate for each of the covered controlled substances from the responses received from state PDMP Administrators, DEA relied upon the number of individuals who received a prescription for a covered controlled substance that met any of the three red-flag metrics for each of calendar years 2022–2024. Using the population of the states responding to DEA's request, DEA then calculated the percentage of the population issued a prescription with a red flag. Using this estimated percentage for 2021–2024, DEA analyzed trends in the data to predict the estimated percentage of patients who would be expected to be included in these red-flag metrics for 2026.

DEA also reviewed aggregate sales data for each of the covered controlled substances, which it extracted from IQVIA's National Sales Perspective.¹¹

¹⁰ Suntree Pharmacy and Suntree Medical Equipment, LLC, 85 FR 73753 (Nov. 19, 2020) (finding that the pharmacy filled prescriptions despite the presence of multiple unresolved red flags, including cash payments); Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy, 83 FR 10876 (Mar. 13, 2018) (revoking pharmacy's registration for filling prescriptions that raised the red flag of customers paying cash for their prescriptions, among other red flags).

¹¹ DEA has purchased this data from IQVIA for decades and routinely uses this information to

IQVIA sales data was selected to help quantify diversion at the national level because it reflects the best national estimate for all prescriptions written and filled, including the total quantity available for diversion or misuse. DEA analyzed trends in IQVIA sales data from January 2021–April 2025, in order to predict the estimated national sales for 2026.

To estimate diversion for each of the covered controlled substances, DEA multiplied the forecasted percentage of patients likely to receive a prescription for a covered controlled substance that meet any of the three red-flag metrics in 2026 by the forecasted sales data from IQVIA for 2026. The resulting estimate of diversion from data submitted by state PDMP Administrators is summarized below in Table 1b. This data contributed to the final diversion estimate set forth in Table 3.

TABLE 1b—DIVERSION ESTIMATES FOR 2026 BASED ON STATE PDMP DATA FOR COVERED CONTROLLED SUBSTANCES FROM 2022–2024.

Controlled substance	(g)
Fentanyl	27
Hydrocodone	124,656
Hydromorphone	477
Oxycodone	302,819
Oxymorphone	0

Consideration of Registrant Reported Diversion in the Legitimate Distribution Chain

DEA extracted data from its Theft Loss Report database and categorized it by each basic drug class. DEA calculated the estimated amount of diversion by multiplying the quantity of API in each finished dosage form by the total amount of units reported stolen or lost to estimate the metric weight in grams of the controlled substance being diverted. Additional data was provided by a DEA field office based on the conclusion of a regulatory inspection. In January 2025, DEA Diversion Investigators conducted an inspection at a DEA-registered pharmaceutical company and discovered a significant quantity of oxycodone medications missing from various production stages. DEA fined the company who surrendered their DEA registration license at the conclusion of the investigation. This estimate of diversion from the legitimate supply chain for each of the covered controlled substances is displayed in Table 2. This

administer several regulatory functions, including the administration of DEA's quota program.

⁸ Frank's Corner Pharmacy, 60 FR 17574 (Apr. 6, 1995); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (Oct. 12, 2012).

⁹ This total does not include insurance co-payments made with cash.

data contributed to the final diversion estimates set forth in Table 3.

TABLE 2—DIVERSION ESTIMATES
BASED ON SUPPLY CHAIN DIVER-
SION DATA FOR COVERED CON-
TROLLED SUBSTANCES

Controlled substance	(g)
Fentanyl	78
Hydrocodone	18,765
Hydromorphone	1,653
Oxycodone	43,978
Oxymorphone	97

In accordance with 21 U.S.C. 826(i), DEA’s estimate of diversion for the five controlled substances was calculated by combining the values in Tables 1b and 2.

TABLE 3—TOTAL ESTIMATES OF DI-
VERSION FOR COVERED CON-
TROLLED SUBSTANCES TO BE CON-
SIDERED IN THE 2026 APQS

Controlled substance	(g)
Fentanyl	105
Hydrocodone	143,421

TABLE 3—TOTAL ESTIMATES OF DI-
VERSION FOR COVERED CON-
TROLLED SUBSTANCES TO BE CON-
SIDERED IN THE 2026 APQS—Con-
tinued

Controlled substance	(g)
Hydromorphone	2,130
Oxycodone	346,797
Oxymorphone	97

*Continuing Efforts To Anticipate and
Prevent Drug Shortages*

DEA remains committed to monitoring drug shortages, limiting their impact, and resolving them as quickly as possible. DEA continues to seek additional information that will assist in accurately forecasting domestic medical usage and export requirements of schedule I or II substances. In February 2024, DEA began utilizing IQVIA’s foreign (non-U.S.) sales tracking data module, MIDAS, which provides valuable insight into the growing export markets for schedule II stimulants. In March 2025, DEA sent a letter requesting approximately 700 DEA-registered manufacturers and

distributors to voluntarily switch their DEA ARCOS database reporting from a quarterly to monthly basis.

On April 29, 2024, DEA announced to DEA-registered manufacturers that procurement quotas for the purpose of commercial manufacturing of schedule II-controlled substances will be allocated on a semi-annual basis, except that procurement quotas relating to injectable drug products will be allocated annually. In a continuing effort to prevent drug shortages and be more agile in its administration of the quota program, DEA will continue to administer applicable procurement quotas on a semi-annual basis. DEA remains committed to ensuring that all patients with legitimate medical need can access appropriately prescribed medications.

The Administrator, therefore, proposes to establish the 2026 APQ for certain schedule I and II controlled substances and AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

BILLING CODE 4410-09-P

Basic Class	Established 2026 Quotas (g)
Schedule I	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	30
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(4-Methoxyphenyl)-N-methylpropan-2-amine (Paramethoxymethamphetamine)	30
1-(5-Fluoropentyl)-3-(1-naphthoyl) indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole (AM694)	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2'-Fluoro 2-fluorofentanyl	30
2,5-Dimethoxy-4-Ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-[N]-Propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-(2,5-Dimethoxy-4-(N)-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Ethoxybenzyl)-5-Nitro-1-(2-(Piperidin-1-yl)Ethyl)-1H-Benzimidazole (N-Piperidinyl Etonitazene)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(Ethylamino)-2-(3-Methoxyphenyl)Cyclohexan-1-One (Methoxetamine)	30
2-Methyl AP-237	30
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	12,000

3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	30,000
3,4-Methylenedioxymethamphetamine (MDMA)	12,000
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
3-Methylmethcathinone	30
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
4'-Methyl acetyl fentanyl	30
4'-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4,4'-Dimethylaminorex	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	5,100
4-CN-Cumyl-Butinaca	25
4-Fluoroisobutyl fentanyl	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methyl-alpha-ethylaminopentiophenone (4-MEAP)	25
4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP)	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methylaminorex	25
4F-MDMB-BUTICA	30
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
5-Fluoro-PB-22; 5F-PB-22	25
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	30,000
5F-AB-PINACA ; (1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	25
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	25
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	25
5F-CUMYL-P7AICA; 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-	25

3carboximide	
5F-CUMYL-PINACA	25
5F-EDMB-PICA	30
5F-EDMB-PINACA	25
5F-MDMB-PICA	25
A-PIHP; 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (alpha-PiHP)	30
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB-4en-PINACA	30
ADB-BUTINACA	30
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
All other tetrahydrocannabinol	1,166,130
Allylprodine	25
alpha-Ethyltryptamine	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α -PBP)	25
alpha-pyrrolidinoheptaphenone (PV8)	25
alpha-pyrrolidinohexabophenone (alpha-PHP)	25
alpha-Pyrrolidinopentiophenone (α -PVP)	25
Alphacetylmethadol	25
Alphameprodine	25
Alphamethadol	25
Amineptine	30
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Beta hydroxy-3-methylfentanyl	30
Beta hydroxyfentanyl	30
Beta-hydroxythiofentanyl	30

Beta-Methyl fentanyl	30
Beta'-Phenyl fentanyl	30
Betacetylmethadol	25
Betameprodine	25
Betamethadol	4
Betaprodine	25
Brorphine	30
Bufotenine	15
Butonitazene	30
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonazepam	30
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25
CUMYL-PEGACLONE	30
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
Delta-9-Tetrahydrocannabinol	1,523,040
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diclazepam	30
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,300
Dihydromorphine	639,954
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	20,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Ethylphenidate	30
Etizolam	30
Etodesnitazene	30
Etonitazene	25
Etorphine	30
Etosexidine	25

Eutylone	30
Fenethylamine	30
Fentanyl carbamate	30
Fentanyl related substances	600
Flualprazolam	30
Flubromazolam	30
Flunitazene	30
FUB-144	25
FUB-AKB48	25
FUB-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	49,675,266
Heroin	150
Hydromorphanol	40
Hydroxypethidine	25
Ibogaine	210
Isobutyryl Fentanyl	25
Isotonitazene	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenyacetylmorphan	25
Lysergic acid diethylamide (LSD)	1,200
MAB-CHMINACA; ADB-CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
Marijuana	6,675,000
Marijuana extract	1,000,000
MDMB-4EN-PINACA	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
Mecloqualone	30
Mescaline	1,200

Mesocarb	30
Methaqualone	60
Methcathinone	25
Methiopropamine	30
Methoxyacetyl fentanyl	30
Methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (4F-MDMB-BINACA)	30
Methyldesorphine	5
Methyldihydromorphine	25
Metodesnitazene	30
Metonitazene	30
MMB-CHMICA; (AMB-CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
MMB-FUBICA	30
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
N,N-Dimethylamphetamine	25
N-Ethyl-1-phenylcyclohexylamine; N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine; N-Desethyl Isotonitazene	30
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
N-Methyl-3-piperidyl benzilate	30
N-Pyrrolidino Etonitazene	30
Naphyrone	25
Nicocodeine	25
Nicomorphine	25
NM2201: Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	25
Noracymethadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
ortho-Fluoroacryl fentanyl	30
ortho-Fluorobutyl fentanyl	30

Ortho-Fluorofentanyl,2-Fluorofentanyl	30
ortho-Fluoroisobutyl fentanyl	30
ortho-Methyl acetylfentanyl	30
ortho-Methyl methoxyacetyl fentanyl	30
Para-Chloroisobutyl fentanyl	30
Para-Flourobutyl fentanyl	25
Para-Fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyl fentanyl	30
para-Methylfentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphane	25
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Protonitazene	30
Psilocybin	40,000
Psilocyn	48,000
Racemoramide	25
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrofuran fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
Thiofuranyl fentanyl	30
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
U-47700	30
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
Valeryl fentanyl	25
Zipeprol	30

Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	937,874
Alfentanil	5,000
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	942,452
Codeine (for sale)	19,262,516
d-Amphetamine (for conversion)	29,171,447
d-Amphetamine (for sale)	26,450,000
d-Methamphetamine (for conversion)	485,020
d-Methamphetamine (for sale)	47,000
d,l-Amphetamine	21,200,000
d,l-Methamphetamine	150
Dexmethylphenidate (for conversion)	5,374,683
Dexmethylphenidate (for sale)	6,200,000
Dextropropoxyphene	35
Dihydrocodeine	115,227
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	60,492
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	731,236
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	26,978,077
Hydromorphone	1,949,378
Isomethadone	30
l-Amphetamine	30
l-Methamphetamine	587,229
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	20,000
Lisdexamfetamine	42,057,460
Meperidine	681,184
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30

Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
Methamphetamine	150
Methylphenidate (for conversion)	19,975,468
Methylphenidate (for sale)	58,283,000
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,393,200
Morphine (for sale)	20,689,632
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	24,756,979
Noroxymorphone (for sale)	2,500
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	37,721,950
Oxycodone (for conversion)	437,827
Oxycodone (for sale)	50,237,652
Oxymorphone (for conversion)	31,773,105
Oxymorphone (for sale)	464,367
Pentobarbital	40,000,000
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	100
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanyl	4,000
Secobarbital	172,100
Sufentanyl	4,000
Tapentadol	10,390,226
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	41,100
Ephedrine (for sale)	3,933,336
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	186,617,466

CFR 1308.11 and 1308.12 remain at zero.

These proposed 2026 quotas reflect the quantities that DEA believes are necessary to meet the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements; and the establishment and maintenance of reserve stocks.

In accordance with 21 CFR 1303.13 and 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2026 APQ and AAN as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will issue and publish in the **Federal Register** a final order establishing the 2026 APQ for controlled substances in schedules I and II and establishing an AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as directed by 21 CFR 1303.11(c) and 1315.11(f).

Signing Authority

This document of the Drug Enforcement Administration was signed on November 25, 2025, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–21509 Filed 11–25–25; 4:15 pm]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB 1140–0102]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Title— Revision of a Previously Approved Collection; Explosives Licensee/ Permittee Out-of-Business Records

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives; Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), will be submitting the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: ATF encourages comments on this information collection. You may submit written comments until midnight on January 27, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection to Matthew Grim, by email to ntcobrc@atf.gov, or by mail to National Tracing Center; 244 Needy Road, Martinsburg, WV 25405. Identify comments by the OMB control number 1140–0102. You may view the proposed information collection instrument online at <https://www.atf.gov/rules-and-regulations/federal-register-actions/forms-and-information-collection>.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, contact: Matthew Grim, Out-of-Business Records Center, either by mail at National Tracing Center; 244 Needy Road, Martinsburg, WV 25405, by email at ntcobrc@atf.gov, or telephone at 800–788–7133, ext. 03683.

SUPPLEMENTARY INFORMATION: We encourage written comments and suggestions from the public and affected agencies concerning the proposed information collection. Your comments should address one or more of the following four points:

- Evaluate whether the proposed information collection is necessary to properly perform ATF's functions, including whether the information will have practical utility;
- Evaluate the agency's estimate of the proposed information collection's burden for accuracy, including validity of the methodology and assumptions used;
- Evaluate whether, and if so, how, the quality, utility, and clarity of the collected information can be enhanced; and
- Minimize the information collection's burden on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting people to submit electronic responses.

Abstract: Regulations under 27 CFR 555.128 require explosives licensees/ permittees to transfer required records to the ATF Out-of-Business Records Center when they discontinue business without a successor. The records on licensee/permittee importing, manufacturing, shipping, receiving, selling, or otherwise disposing of explosive materials aid ATF in conducting investigations into trafficking and other criminal misuse of explosives.

Overview of This Information Collection

1. *Type of information collection:* revision of a previously approved collection.

2. *The title of the form/collection:* Explosives Licensee/Permittee Out-of-Business Records.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: ATF Form none.

Component: Bureau of Alcohol, Tobacco, Firearms, and Explosives; U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* individuals or households, private sector for- or not-for-profit institutions. The obligation to respond is mandatory per § 555.121.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 250 respondents will respond to this collection when they discontinue business, and it will take each respondent approximately 30 minutes (0.5 hours) to complete their responses.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 115 total hours, which is equal to 230 (total respondents) * 1 (# of responses per respondent) * 0.5 hours (30 minutes).

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* Based on records over the past three years, most out-of-business records are submitted in electronic form, but some licensees/permittees augment with remaining paper records. They submit these paper records in a large envelope. ATF estimates that capital costs to submit out-of-business records are \$1.27 for a large envelope. At 230 annual responses, ATF estimates that the capital cost for this information collection renewal is \$292.

ESTIMATED ANNUALIZED RESPONDENT COST AND HOUR BURDEN
[Rounded]

Activity	Number of respondents	Frequency	Total annual responses	Time per response (hours)	Total annual burden (hours)
Submit out-of-business records	230	1	230	0.5	115

Revisions to This Information Collection

ATF is revising this information collection, OMB control number 1140–0102, to reflect a decrease in the number of explosives licensees/permittees going out of business over the past three years. This change has also resulted in a corresponding decrease in public burden hours, reducing the number of respondents along with the shipping and mailing cost burden. In addition, this renewal includes a monetized value for the time burden, based on a new request from OMB, and the title has been slightly modified to clarify that it applies to explosives licensees/permittees.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer; United States Department of Justice; Justice Management Division, Enterprise Portfolio Management; Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: November 24, 2025.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2025–21338 Filed 11–26–25; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB 1140–0010]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Application to Transport Interstate or To Temporarily Export Certain NFA Firearms—ATF Form 5320.20

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), will be submitting the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: ATF encourages comments on this information collection. You may submit written comments until midnight on January 27, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection to Meghan Tisserand, Division Staff, National Firearms Act Division, either by mail at National Firearms Act Division; Division Staff Office; 244 Needy Road; Martinsburg, WV 25405, by email at meghan.tisserand@atf.gov, or by telephone at 304.616.3219. Identify comments by the OMB control number 1140–0010. You may view the proposed information collection instrument online at <https://www.atf.gov/rules-and-regulations/federal-register-actions/forms-and-information-collection> under the month in which this notice was published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, contact: Meghan Tisserand, Division Staff, National Firearms Act Division, either by mail at National Firearms Act Division; Division Staff Office; 244 Needy Road; Martinsburg, WV 25405, by email at Meghan.tisserand@atf.gov, or by telephone at 304.616.3219.

SUPPLEMENTARY INFORMATION: We encourage written comments and suggestions from the public and affected agencies concerning the proposed information collection. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary to properly perform ATF's functions, including whether the information will have practical utility;
- Evaluate the agency's estimate of the proposed information collection's burden for accuracy, including the validity of the methodology and assumptions used;
- Evaluate whether, and if so, how the quality, utility, and clarity of the collected information can be enhanced; and

—Minimize the information collection's burden on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Abstract:* Persons who wish to transport certain NFA firearms (machine guns, short-barreled rifles, short-barreled shotguns, or destructive devices) out of the state in which they registered the firearm, for certain temporary or permanent domestic purposes or for temporary export, must submit ATF Form 5320.20 ("Form 20") to ATF before they may transport the items. 18 U.S.C. 922(a)(4), 27 CFR 478.28.

2. *Type of information collection:* Revising a previously approved collection.

3. *Title of the form/collection:* Application to Transport Interstate or to Temporarily Export Certain NFA Firearms.

4. *Agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5320.20.

Component: Bureau of Alcohol, Tobacco, Firearms, and Explosives.

5. *Affected public who will be asked or required to respond, as well as the obligation to respond:*

Affected Public: state, local, and tribal governments, individuals or households, private sector for-profit institutions, federal government.

Obligation to respond: voluntary, and required to obtain or retain benefits.

6. *Estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 12,878 respondents will complete this form once annually, and it will take each respondent approximately 0.167 hours to complete their responses.

7. *Estimate of the total annual burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 2,151 total hours, which is equal to 12,878

(total respondents) * 1 (# of responses per respondent) * 0.167 hours.

8. *Estimate of the total annual other cost burden associated with the collection, if applicable: \$0.*

ESTIMATED TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response (hours)	Total annual burden (hours)
Completing Form 20	12,878	1	12,878	0.167	2,151
Unduplicated Totals			12,878	0.167	2,151

Revisions to This Information Collection

ATF is revising this information collection, OMB control number 1140–0010, to make the form electronically fillable and allow it to be submitted by email. In addition, ATF will have made the form part of its online eForms platform by the time this ICR completes the renewal process, both of which result in full electronic submission. In the process of these changes, ATF has also made the second copy automatically auto-fill, when it was previously completed by the respondent in addition to the primary form. ATF also made some additional small edits to the form to make it easier to read and made a slight revision to the title to clarify the type of transportation covered.

The changes to the form due to updated technology have decreased the time necessary to complete the form, which was previously 20 minutes (ten minutes were attributed to addressing and mailing) and has now decreased to ten minutes. In addition, respondents no longer incur mailing time and costs. There has also been a decrease in the number of respondents per year, from 20,000 respondents during the last renewal to 12,878 during this renewal, a decrease of 7,122 respondents. These combined changes have resulted in a decrease in total annual burden hours from 6,667 hours to 2,151, a decrease of 4,516 hours, and a corresponding decrease in the monetized time value for this ICR.

If you require additional information, contact: Darwin Arceo, Department Clearance Officer; United States Department of Justice; Justice Management Division, Enterprise Portfolio Management; Two Constitution Square; 145 N Street NE, 4W–218; Washington, DC.

Dated: November 25, 2025.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2025–21512 Filed 11–26–25; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB 1140–0055]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Title—Identifying/Marking Explosive Materials

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives; Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), will be submitting the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: ATF encourages comments on this information collection. You may submit written comments until midnight on January 27, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection to Andy Stephenson, Explosives Enforcement Specialist, by email to andrew.stephenson@atf.gov, or by mail to 99 New York Ave. NE; Room 6.N.518; Washington, DC 20226. Identify comments by the OMB control number 1140–0055. You may view the proposed information collection instrument online at <https://www.atf.gov/rules-and-regulations/federal-register-actions/forms-and-information-collection>.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the

proposed information collection instrument with instructions or additional information, contact: Andy Stephenson, either by mail at EIPB, 99 New York Ave. NE; Room 6.N.518; Washington, DC 20226, by email at eipb-informationcollection@atf.gov, or by telephone at 202–272–5355.

SUPPLEMENTARY INFORMATION: We encourage written comments and suggestions from the public and affected agencies concerning the proposed information collection. Your comments should address one or more of the following four points:

- Evaluate whether the proposed information collection is necessary to properly perform ATF's functions, including whether the information will have practical utility;
- Evaluate the agency's estimate of the proposed information collection's burden for accuracy, including validity of the methodology and assumptions used;
- Evaluate whether, and if so, how, the quality, utility, and clarity of the collected information can be enhanced; and
- Minimize the information collection's burden on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting people to submit electronic responses.

Abstract: To protect the public from misuse of explosives, implementing regulations at 27 CFR 555.109 require licensees/permittees to mark certain explosives they manufacture or import, as well as mark immediate containers and outside packaging. The markings must include certain information and be clear and permanent, though they can be done via sticky label, marker, etc. Some types of explosives are too small or too fluid to be marked, or in a form that cannot be marked, and are therefore excepted from the marking requirements.

Overview of This Information Collection

1. *Type of information collection:* revision of a previously approved collection.

2. *The title of the form/collection:* Identifying/Marking Explosive Materials.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: none.

Component: Bureau of Alcohol, Tobacco, Firearms, and Explosives; U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* private sector for-profit institutions. The obligation to respond is mandatory per 27 CFR part 555.109.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 103 respondents will respond to this collection 520 times

annually, and it will take each respondent approximately 0.000834 (3 seconds) to complete their responses.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 45 total hours, which is equal to 103 (total respondents) * 520 (# of responses per respondent) * 0.000834 (3 seconds).

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$0.

ESTIMATED ANNUALIZED RESPONDENT COST AND HOUR BURDEN

[Rounded]

Activity	Number of respondents	Frequency (times/year)	Total annual responses	Time per response (hours)	Total annual burden (hours)
Marking explosive materials	103	520	53,560	0.000834	45

Revisions to This Information Collection

This information collection, OMB control number 1140–0055, previously covered only manufacturer markings, and another information collection, 1140–0062, covered importer markings. However, to streamline the two information collections and eliminate redundancies that have evolved, ATF has decided to combine the two ICRs and has slightly revised the title to no longer limit it to manufacturers. ICR 1140–0055 is now the resulting combined ICR. In addition, the number of licensees/permittees in both groups has decreased a small amount since the last renewal for each ICR, for a combined decrease in licensees/permittees from 2,066 to 2,054, or a decrease of 12. In addition, ATF has updated the ICR to account for only the portion of these licensees/permittees that actually manufacture or import and distribute the kinds of explosives they are required to mark, which is five percent of the total licensees/permittees registered to manufacture or import, resulting in a further decrease in respondents affected by this information collection to 103 total. Consequently, the total responses and burden hours have also decreased due to the reduced number of respondents, from 895 hours to 45, or a reduction of 850 hours. In addition, due to a new request by OMB, the agency is including in the ICR a monetized value for the time, which it had not included in previous ICRs.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer; United States Department of Justice; Justice

Management Division, Enterprise Portfolio Management; Two Constitution Square, 145 N Street NE, 4W–218; Washington, DC.

Dated: November 25, 2025.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2025–21410 Filed 11–26–25; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB 1140–0091]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Title—National Response Team Customer Satisfaction Survey

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives; Department of Justice

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), will be submitting the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: ATF encourages comments on this information collection. You may submit written comments until midnight on January 27, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection to Jennifer George, Analyst, Fire Investigation and

Arson Enforcement Division Program, by email to jennifer.george@atf.gov, or by mail to Corporal Road, Building 3750; Redstone Arsenal; Huntsville, AL 35898. Identify comments by the OMB control number 1140–0091 You may view the proposed information collection instrument online at <https://www.atf.gov/rules-and-regulations/federal-register-actions/forms-and-information-collection>.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, contact: Jennifer George, NCETR, either by mail at Corporal Road, Building 3750; Redstone Arsenal; Huntsville, AL 35898, by email at jennifer.george@atf.gov, or by telephone at 256–261–7614.

SUPPLEMENTARY INFORMATION: We encourage written comments and suggestions from the public and affected agencies concerning the proposed information collection. Your comments should address one or more of the following four points:

- Evaluate whether the proposed information collection is necessary to properly perform ATF's functions, including whether the information will have practical utility;
- Evaluate the agency's estimate of the proposed information collection's burden for accuracy, including validity of the methodology and assumptions used;
- Evaluate whether, and if so, how, the quality, utility, and clarity of the

collected information can be enhanced; and

- Minimize the information collection's burden on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting people to submit electronic responses.

Abstract: ATF requests feedback on NRT's effectiveness, performance, strengths, weaknesses, etc., from organizations that request the NRT's investigative and crime scene services in responding to arson and explosives events. The information is used for internal audits that support the NRT's national-level forensics accreditation.

Overview of This Information Collection

1. *Type of information collection:* revision of a previously approved collection.

2. *The title of the form/collection:* National Response Team Customer Satisfaction Survey.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: none.

Component: Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* state, local and tribal governments. The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 18 respondents will provide information to complete this survey once annually, and it will take each respondent approximately 0.25 hours to complete their responses.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 5 total hours, which is equal to 18 (total respondents) * 1 (# of responses per respondent) * 0.25 (15 minutes).

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$0.

ESTIMATED ANNUALIZED RESPONDENT COST AND HOUR BURDEN [Rounded]

Activity	Number of respondents	Frequency	Total annual responses	Time per response (hours)	Total annual burden (hours)
Completing SurveyMonkey survey	18	1	18	0.25	5
Unduplicated totals	18		18	0.25	5

Revisions to This Information Collection

ATF is revising this ICR, OMB control number 1140-0091, to reflect a change from surveys by mail through emailed surveys to now online surveys. In addition, ATF has streamlined the invitation process. As a result of these changes, the time burden for individual respondents has decreased from .5 hours to .25 hours. In addition, the number of arson and explosives crime scene events was lower during the past three years, resulting in a decrease in the annual number of respondents, from 32 in 2022 to 18, a decrease of 14 respondents. These combined changes have resulted in a corresponding decrease in total hourly burden from 16 to five, a decrease of 11 hours. In addition, ATF has added a monetized value for the time burden, due to new OMB request, which has not been in previous ICRs.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer; United States Department of Justice; Justice Management Division, Enterprise Portfolio Management; Two Constitution Square, 145 N Street NE, 4W-218; Washington, DC.

Dated: November 24, 2025.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2025-21339 Filed 11-26-25; 8:45 am]

BILLING CODE 4410-CW-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-0381]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Juvenile Facility Census Program (JFCP)

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The National Institute of Justice, Office of Justice Programs, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until December 29, 2025.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated

response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Benjamin Adams, Supervisory Social Science Analyst, National Institute of Justice, 999 North Capitol Street NE, Washington, DC 20531 (email: benjamin.adams@usdoj.gov; telephone: 202-598-6493).

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on May 21, 2024, 89 FR 44709, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and/or

—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.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the information collection or the OMB Control Number [1121–0381]. This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for two (2) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision to currently approved collection.

2. *Title of the Form/Collection:* Juvenile Facility Census Program (JFCP).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form numbers are CJ–14 (Youth Characteristics Module) and CJ–15 (Facility Operations Module). The applicable components within the Department of Justice are the National Institute of Justice and the Office of Juvenile Justice and Delinquency Prevention, in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* State, local and tribal governments, individuals or households, and Private Sector-for or not for profit institutions.

Abstract: This request for clearance of the Juvenile Facility Census Program (JFCP) will combine two previously, separately cleared data collections: the Census of Juveniles in Residential Placement (CJRP, OMB # 1121–0218)

and the Juvenile Residential Facility Census (JRFC, OMB # 1121–0219). The JFCP collects information from all secure and nonsecure residential placement facilities that house persons younger than age 21 who are being held as a result of some contact with the juvenile justice system for a law violation. This encompasses both status offenses and delinquency offenses and includes youth who are either temporarily detained by the court or committed after adjudication for an offense. The JFCP consolidates the content of the CJRP and JRFC into a single, unified program. It collects general information on facility characteristics and the number of youth housed, and includes two rotating content modules that are administered separately during a two-year collection cycle: the Youth Population module and the Facility Operations module. The Youth Population module collects detailed information on individual youth housed in facilities, including demographic details, placement characteristics, and length of stay. The Facility Operations module collects information on resident services, facility features, and operations. The information gathered in these national collections will be used in published reports and statistics. The reports will be made available to the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, others interested in juvenile residential facilities, and the general public via the OJP agency websites. The two data collections are being consolidated to attain cost savings and reduce respondent burden.

5. *Obligation to Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* The total estimated respondents is 1,636 for each module for each year.

7. *Estimated Time per Respondent:* It takes an average of 6 hours to complete the JFCP. The total burden is 9,816, including the two rotating content modules that are administered separately during a two-year collection cycle. The Youth Characteristics module takes an average of 4 hours to complete. The total burden for the Youth Characteristics module is 6,544 hours. The Facility Operations module takes an average of 2 hours to complete. The total burden for the Facility Operations module is 3,272 hours.

8. *Frequency:* The JFCP is a biennial data collection with two content modules administered separately during a two-year collection cycle.

9. *Total Estimated Annual Time Burden:* The average annual burden is

4,908 or 9,816 total hours for the two-year collection cycle.

10. *Total Estimated Annual Other Costs Burden:* The estimated annual cost for JFCP is \$1,142,115. The estimated cost for one collection cycle is \$2,284,230.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Enterprise Portfolio Management, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 25, 2025.

Darwin Arceo,
Department Clearance Officer for PRA, U.S.
Department of Justice.

[FR Doc. 2025–21575 Filed 11–26–25; 8:45 am]

BILLING CODE 4410–18–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 99902080; NRC–2025–1171]

Atomic Alchemy Operators LLC; VIPR Idaho LLC; Construction Permit Application

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing public notice of receipt and availability for the first part of a construction permit application for a four-unit reactor facility from Atomic Alchemy Inc. on behalf of Atomic Alchemy Operators LLC and VIPR Idaho LLC. The first part of the construction permit application was received on September 12, 2025.

DATES: November 28, 2025.

ADDRESSES: Please refer to Docket ID NRC–2025–1171 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–2025–1171. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual listed in the “For Further Information Contact” section of this document.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at

<https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Linh Tran, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-4103; email: Linh.Tran@nrc.gov.

I. Discussion

On September 12, 2025, Atomic Alchemy Inc., on behalf of Atomic Alchemy Operators LLC and VIPR Idaho LLC, transmitted to the NRC the first part of an application, pursuant to section 103 of the Atomic Energy Act of 1954, as amended, and part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Production and Utilization Facilities," for a construction permit for a four-unit, non-power, light-water-cooled, pool-type Versatile Isotope Production Reactor (VIPR) facility to be located at the Idaho National Laboratory desert site, in Bingham County, Idaho. Each VIPR unit utilizes low-enriched fuel and contains irradiation positions for radiating targets. The VIPR units and related processing hot cells and target fabrication are referred to as the Meitner-1 facility.

As part of the construction permit application, Atomic Alchemy Inc., on behalf of Atomic Alchemy Operators LLC and VIPR Idaho LLC, requested an exemption from certain requirements of 10 CFR 2.101(a)(5) that would allow the submission of the second part of the application, the environmental report, within six months of the first part.

The first part of the construction permit application and the exemption request are available in ADAMS under Accession Nos. ML25255A199 (package) and ML25255A203, respectively.

The NRC staff is currently reviewing the exemption request and undertaking its acceptance review of the first part of

the construction permit application. If the exemption request is granted and the application is accepted for docketing, a subsequent **Federal Register** notice will be issued that addresses the acceptability of the first part of the application for docketing and provisions for participation of the public in the permitting process.

A **Federal Register** notice of receipt and availability for the second part of the construction permit application will be issued after the NRC receives the second part of the application. If the second part of the application is accepted for docketing, a subsequent **Federal Register** notice will be issued that addresses the acceptability of the second part of the application for docketing and provisions for participation of the public in the permitting process.

Dated: November 24, 2025.

For the Nuclear Regulatory Commission.

Jeffrey Rady,

Chief, Non-Power Production and Utilization Facilities Licensing Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2025-21401 Filed 11-26-25; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-608; NRC-2021-0140]

SHINE Technologies, LLC; SHINE Medical Isotope Production Facility; Environmental Assessment and Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) regarding the SHINE Technologies, LLC (SHINE, the licensee) request to amend Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility (SHINE facility) in Rock County, Wisconsin. The amendment request seeks NRC approval to extend the latest date for completion of the construction of the SHINE facility from December 31, 2025, to December 31, 2029.

DATES: The EA and FONSI referenced in this document are available on November 28, 2025.

ADDRESSES: Please refer to Docket ID NRC-2021-0140 when contacting the NRC about the availability of

information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2021-0140. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Balazik, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2856; email: Michael.Balazik@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of an amendment to Construction Permit No. CPMIF-001, issued to SHINE for the construction of the SHINE facility in Rock County, Wisconsin. SHINE requested the amendment by letter dated August 14, 2025, in accordance with section 50.90 of title 10 of the *Code of Federal Regulations* (10 CFR), "Application for amendment of license, construction permit, or early site permit," and 10 CFR 50.55(b). The amendment would extend the latest date for completion of the construction of the SHINE facility from December 31, 2025, to December 31, 2029.

In accordance with 10 CFR 51.21, "Criteria for and identification of

licensing and regulatory actions requiring environmental assessments,” the NRC prepared an EA, pursuant to 10 CFR 51.30, “Environmental assessment,” that analyzes the environmental impacts of the proposed amendment and alternatives, as appropriate. Based on the results of this EA, which is set forth in section II of this document, and in accordance with 10 CFR 51.31(a), the NRC has determined not to prepare an environmental impact statement for the proposed amendment and is issuing a FONSI, which is set forth in section III of this document.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would amend Construction Permit No. CPMIF-001 to extend the latest date for completion of the construction of the SHINE facility from December 31, 2025, to December 31, 2029. The proposed action is requested in the licensee’s application dated August 14, 2025.

The proposed action would not allow any work to be performed that is not already authorized by the construction permit. The proposed action would grant SHINE more time to complete the construction of the SHINE facility in accordance with the construction permit.

Need for the Proposed Action

SHINE completed a review of the construction schedule for the SHINE facility and determined that construction will not be completed by December 31, 2025, the latest date for completion of the construction of the SHINE facility prescribed by the construction permit. SHINE stated that developmental effort delays have occurred due to the first-of-a-kind nature of the SHINE facility, including efforts contributing to engineering detailed design progression, procurement of unique and one-of-a-kind components, construction of a first-of-a-kind facility, and progression of an operating license application that has no precedent. SHINE now expects the construction of the SHINE facility to be substantially completed in 2027, and the remaining uncompleted items of construction completed in 2029. To accommodate this construction schedule and to incorporate conservatism, SHINE is requesting to extend the latest date for completion of the construction of the SHINE facility to December 31, 2029.

The NRC regulation in 10 CFR 50.55(b) states that upon good cause shown, the Commission will extend the

completion date for a reasonable period of time and that the Commission will recognize, among other things, “developmental problems attributable to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder,” as a basis for extending the completion date.

Environmental Impacts of the Proposed Action

The NRC has completed its environmental review of the proposed action and concludes that there are no significant environmental impacts associated with the proposed action.

The proposed action would only extend the period of construction activities already authorized by the construction permit and would not authorize any new construction activities, any additional land disturbance, or any modifications to the facility from the terms in the construction permit.

In 2015, the NRC evaluated the environmental impacts associated with constructing, operating, and decommissioning the SHINE facility in NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility.” NUREG-2183 concluded that the environmental impacts associated with the construction of the SHINE facility would be small for all resource areas with the exception of traffic, which would incur moderate impacts. In 2022, the NRC issued NUREG-2183, Supplement 1, “Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility: Draft Report for Comment,” which updated NUREG-2183 and only covered matters that differ from those or that reflect significant new information relative to that discussed in NUREG-2183. NUREG-2183, Supplement 1 considered any different information since NUREG-2183 and concluded that there is no significant new information with respect to the environmental impacts of the SHINE facility.

In May 2019, SHINE commenced site-preparation work and NRC-authorized construction of the exterior of the SHINE facility. SHINE completed the construction of the main production facility building in March 2021. Therefore, most of the construction impacts discussed in NUREG-2183 and NUREG-2183, Supplement 1 have already occurred. Since the proposed action would only extend the period of already authorized construction

activities, it does not involve any different impacts or significant changes to those impacts described and analyzed in the previous environmental documents. Therefore, there would be no significant non-radiological or radiological environmental impacts associated with the proposed action. Specifically:

- The proposed action would not result in additional worker vehicles, additional truck deliveries, new land disturbance, new construction, or modification of the SHINE facility from what was previously assessed in NUREG-2183 and NUREG-2183, Supplement 1.

- No changes to the facility’s Wisconsin Pollutant Discharge Elimination System permit are needed.

- There would be no changes to the types or quantity of non-radiological effluents previously assessed in NUREG-2183 and NUREG-2183, Supplement 1.

- The proposed action would not represent a change in the types or quantity of radioactive materials in effluents, wastes, and products of the SHINE facility.

- SHINE must continue to comply with occupational dose limits for adults (10 CFR part 20, subpart C) and radiation dose limits for individual members of the public (10 CFR part 20, subpart D) at all times.

- The proposed action would not have a significant adverse effect on the probability of an accident occurring.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (*i.e.*, the “no-action” alternative). Denial of the amendment request would result in the licensee being unable to complete construction and begin operation of the SHINE facility. However, because the direct impacts on land use and water resources from construction have largely already occurred and because the remaining construction, operating, and decommissioning impacts would generally be small as evaluated in NUREG-2183 and NUREG-2183, Supplement 1, the environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

There are no unresolved conflicts concerning alternative uses of available resources under the proposed action. The proposed action does not involve the use of any resources not previously considered in NUREG-2183 and NUREG-2183, Supplement 1.

Agencies and Persons Consulted

No additional agencies or persons were consulted regarding the environmental impact of the proposed action. On November 17, 2025, the NRC notified the Wisconsin Department of Health Services of the EA and FONSI. The state provided no comments. The NRC staff determined that the proposed action would have no effect on Federally listed threatened or endangered species or critical habitat that could occur on or near the SHINE facility site and would have no effect on any historic properties. Therefore, consultation was not required under section 7 of the Endangered Species Act of 1973, as amended, or under section 106 of the National Historic Preservation Act of 1966, as amended.

III. Finding of No Significant Impact

The proposed action is the issuance of an amendment to SHINE Construction Permit No. CPMIF-001 to extend the latest date for completion of the construction of the SHINE facility from

December 31, 2025, to December 31, 2029. Consistent with 10 CFR 51.21, the NRC prepared an EA to determine the impacts of the proposed action. On the basis of the EA included in section II of this document and incorporated by reference in this finding, the NRC concludes that the proposed action would not have a significant adverse effect on the probability of an accident occurring and would not have any significant radiological or non-radiological impacts. Therefore, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Other than the application dated August 14, 2025, the related environmental documents are NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility," and NUREG-2183, Supplement 1, "Environmental Impact

Statement Related to the Operating License for the SHINE Medical Isotope Production Facility: Draft Report for Comment," which provide the latest environmental review of the construction, operation, and decommissioning of the SHINE facility and description of the environmental conditions at the SHINE facility site.

This EA and FONSI and other related documents are accessible online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR reference staff at 1-800-397-4209 or 301-415-4737, or by email to PDR.Resource@nrc.gov.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS, as indicated.

Document	ADAMS accession No.
NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility," dated October 2015.	ML15288A046
NUREG-2183, Supplement 1, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility: Draft Report for Comment," dated June 2022.	ML22179A346
Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, dated February 29, 2016	ML16041A471
SHINE Medical Technologies, LLC—Issuance of Order and Amendment No. 3 to Construction Permit No. CPMIF-001, dated November 30, 2022.	ML22292A319
SHINE Technologies, LLC Request to Amend Construction Permit No. CPMIF-001, dated August 14, 2025	ML25226A150

Dated: November 25, 2025.
For the Nuclear Regulatory Commission.
Jeffrey Rady,
Chief, Non-Power Production and Utilization Facility Licensing Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.
[FR Doc. 2025-21436 Filed 11-26-25; 8:45 am]
BILLING CODE 7590-01-P

PUBLIC BUILDINGS REFORM BOARD

Notice of Public Meeting by the Public Buildings Reform Board

AGENCY: Public Buildings Reform Board.
ACTION: Notice of public meeting.

SUMMARY: As provided by the Federal Assets Sale and Transfer Act of 2016 (FASTA), the Public Buildings Reform Board (PBRB) is holding its twelfth public meeting. At this meeting, the Board will discuss the progress of past rounds and well as plans for a future round.

DATES: The meeting is scheduled for Thursday, January 29, 2026 from 10:00 a.m. to 11:00 a.m. (Eastern time).
ADDRESSES: The meeting will be held at the Charleston Gaillard Center, 95 Calhoun Street, Charleston, South Carolina 29401.
FOR FURTHER INFORMATION CONTACT: Paul Walden, PBRB, at (202) 716-8165, or questions and comments can be forwarded to the PBRB team at fastainfo@pbrb.gov.

SUPPLEMENTARY INFORMATION:
Background: FASTA created the PBRB as an independent Board to identify opportunities for the Federal government to significantly reduce its inventory of civilian real property and thereby reduce costs. The Board is directed, within 6 months of its formation, to recommend to the Office of Management and Budget (OMB) the sale of not fewer than five properties not on the list of surplus or excess with a fair market value of not less than \$500 million and not more than \$750 million. The Board, to date, has submitted three rounds of recommendations. The

Thomas R. Carper Water Resources Development Act of 2024 (WRDA) extended the Board to December 31, 2026 and allows for the submission of one additional round of recommendations (Round 3).

Format and Registration: The format for the meeting will be panel discussions with appropriate time allowed for a Q&A segment. Participants may also view the meeting virtually. Interested participants must register for the public meeting via this link: <https://forms.gle/DTN1LCd4gDucTYWY9>.

Individuals wishing to attend who require special assistance or accommodations must contact the PBRB Team at fastainfo@pbrb.gov at least 12 days prior to the event.

Portions of the meeting may be held in executive session if the Board is considering issues involving classified or proprietary information.

A transcript of the public meeting will be uploaded to pbrb.gov shortly after the session.

If you have any additional questions, please email fastainfo@pbrb.gov.

Paul Walden,

*Executive Director, Federal Register Liaison,
Public Buildings Reform Board.*

[FR Doc. 2025–21578 Filed 11–26–25; 8:45 am]

BILLING CODE P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Notice of Request for Information; National Strategic Plan for Advanced Manufacturing

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Request for Information, extension of comment period.

SUMMARY: On behalf of the Subcommittee on Advanced Manufacturing of the National Science and Technology Council, the Office of Science and Technology Policy (OSTP) published a document in the **Federal Register** of June 20, 2025, requesting input from all interested parties on the development of a National Strategic Plan for Advanced Manufacturing. This document extends the deadline for submission of responses.

DATES: The deadline is extended to 11:59 p.m. ET on March 30, 2026.

FOR FURTHER INFORMATION CONTACT: Please email the Advanced Manufacturing National Program Office at amnpo@nist.gov (<mailto:amnpo@nist.gov>) or call Said Jahanmir at 301–975–0844.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 2025, 90 FR 26335, OSTP requested input from all interested parties on the development of a National Strategic Plan for Advanced Manufacturing. Through this Request for Information (RFI), OSTP seeks input from the public regarding Federal programs and activities to advance United States manufacturing competitiveness, including advanced manufacturing research and development that will create jobs, grow the economy across multiple industrial sectors, strengthen national security, and improve healthcare. The public input provided in response to this RFI will inform the development of the National Strategic Plan for Advanced Manufacturing. With this notice, the deadline for responses is extended to March 30, 2026.

(Authority: 42 U.S.C. 6622.)

Dated: November 24, 2025.

Stacy Murphy,

Deputy Chief Operations Officer/Security Officer.

[FR Doc. 2025–21336 Filed 11–26–25; 8:45 am]

BILLING CODE 3270–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104243; File No. SR–NYSEARCA–2025–77]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Shares of the T. Rowe Price Active Crypto ETF Under NYSE Arca Rule 8.201–E (Non-Generic) Commodity-Based Trust Shares

November 24, 2025.

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 November 6, 2025, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the T. Rowe Price Active Crypto ETF (the “Fund”) under NYSE Arca Rule 8.201–E (Non-Generic). The proposed rule change is available on the Exchange’s website at www.nyse.com and 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.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Under NYSE Arca Rule 8.201–E (Non-Generic), the Exchange may propose to list and/or trade pursuant to unlisted trading privileges “Commodity-Based Trust Shares.”⁴ The Exchange proposes to list and trade shares (the “Shares”) of the Fund pursuant to NYSE Arca Rule 8.201–E (Non-Generic).⁵

Description of the Fund

The sponsor of the Fund is T. Rowe Price Sponsor LLC (the “Sponsor”), a Delaware limited liability company. The Fund is a Delaware statutory trust that operates pursuant to a trust agreement (the “Trust Agreement”) between the Sponsor and the trustee for the Fund, CSC Delaware Trust Company (the “Trustee”).

The Fund will have a custodian for its crypto asset⁶ holdings and stablecoins (the “Crypto Custodian”) and a custodian for its cash and cash equivalents holdings (the “Cash Custodian”). T. Rowe Price Associates, Inc. (the “Administrator”) provides administrative services to the Fund.

Each Share issued by the Fund represents a fractional undivided beneficial interest in the net assets of the Fund. The assets of the Fund consist primarily of Eligible Assets (as defined below) held by the Crypto Custodian on behalf of the Fund, and may also include cash, cash equivalents, and/or stablecoins.⁷ “Eligible Assets” are

⁴ Commodity-Based Trust Shares are securities issued by a trust that represent investors’ discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the trust.

⁵ On October 22, 2025, the Fund filed a registration statement on Form S–1 under the Securities Act of 1933 (the “Registration Statement”). The descriptions of the Fund and Shares contained herein are based, in part, on the Registration Statement. The Registration Statement is not yet effective, and the Shares will not trade on the Exchange until such time that the Registration Statement is effective.

⁶ According to the Registration Statement, the Sponsor interprets the term “crypto asset” to mean an asset that (1) is generated, issued, and/or transferred using a blockchain or similar distributed ledger technology network, including, but not limited to, assets known as “tokens,” “digital assets,” “cryptocurrencies,” “virtual currencies,” and “coins,” and (2) relies on cryptographic protocols.

⁷ According to the Registration Statement, cash equivalents include but are not limited to currency, demand deposits with banks or other financial institutions, bank money market accounts, time deposits and CDs with maturities of three months or less. The Fund may only invest in stablecoins (1) that maintain a fully reserved 1:1 ratio to an underlying asset, like U.S. dollars, back up their redemption obligations by a reserve asset, do not

Continued

commodities that the Sponsor has determined meet at least one of the following eligibility criteria:

- The commodity trades on a market that is an Intermarket Surveillance Group (“ISG”) member, from which the Exchange may obtain information about trading in such commodity, at all such times that the commodity is in the Fund’s portfolio;
- The commodity underlies a futures contract that has been made available to trade on a designated contract market (“DCM”) regulated by the Commodity Futures Trading Commission (“CFTC”) for at least six months, provided that the Exchange has a comprehensive surveillance sharing agreement (“CSSA”) in place with such DCM, whether directly or through common ISG membership, at all such times that the commodity is in the Fund’s portfolio;
- At the time the commodity becomes part of the Fund’s portfolio, the economic exposure to such commodity represents at least 40% of the net asset value (“NAV”)⁸ of an exchange-traded fund (“ETF”) that lists and trades on a national securities exchange; or
- The commodity otherwise meets the eligibility criteria for holdings of Commodity-Based Trust Shares pursuant to the generic listing standards for Commodity-Based Trust Shares set forth in NYSE Arca Rule 8.201-E(d)(1) (Generic).

To the extent the Sponsor of the Fund is or becomes registered as a broker-dealer or is affiliated with a broker-dealer, the Sponsor has, or will erect and maintain, a “firewall” between the Sponsor and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition and/or changes to the Fund’s Crypto Asset Holdings.⁹ Any person related to the Sponsor who makes decisions pertaining to the Fund’s Crypto Asset Holdings, or has access to material non-public information regarding the Crypto Asset Holdings, or changes thereto, must be subject to procedures reasonably designed to prevent the use

and dissemination of material non-public information regarding the Crypto Asset Holdings or changes thereto. Any person or entity, including any service provider to the Fund, who has access to material non-public information regarding the Crypto Asset Holdings, or changes thereto, must be subject to procedures reasonably designed to prevent the use and dissemination of material non-public information regarding the Crypto Asset Holdings or changes thereto.

Investment Objective

According to the Registration Statement, the Fund is an actively managed exchange-traded product (“ETP”) that seeks to outperform the FTSE Crypto US Listed Index (the “Index”) over a long term (*i.e.*, typically over a period of a year or longer). The Index is comprised of the top ten crypto assets by market capitalization that (1) the index provider has determined meets the eligibility criteria set forth in NYSE Arca Rule 8.201-E(d)(1) (Generic) for a commodity, or commodity that underlies a commodity-based asset held by a trust issuing Commodity-Based Trust Shares pursuant to such rule; or (2) constitute, or are eligible to constitute, the underlying crypto asset for one or more ETPs or ETFs registered with the Commission (the “Index Constituents”). The Index Constituents must meet minimum market capitalization and liquidity thresholds, as determined by the index provider, and are weighted by the square root of market capitalization based on circulating supply and price. The Index is published daily from Sunday to Friday at 4:00 p.m. E.T. and is rebalanced quarterly. The Fund may use a different index at any time; notification of a change will be made via a prospectus supplement, in the Fund’s periodic Exchange Act reports, and/or on the Fund’s website.

The Fund will only invest in Eligible Assets and, under normal circumstances, is expected to hold between five and 15 crypto assets, but may hold fewer than five or more than 15 at any time. In seeking to achieve its investment objective, the Fund will employ an active investment strategy and may invest in the Index Constituents in the same or different proportions as the Index. The Fund may invest in one or more Index Constituents in excess of or below the weight assigned to such Index Constituents, invest in one or more crypto assets that are not Index Constituents, or determine not to invest in one or more crypto assets that are Index Constituents. The Fund may use

one or more of its Eligible Assets to purchase other Eligible Assets and may engage in trading of Eligible Assets on both U.S. and non-U.S. crypto trading platforms. However, the Fund will not invest in any crypto asset that is not an Eligible Asset.

The Fund intends to achieve its objective by primarily investing in a diversified basket of crypto assets. Consistent with its investment objective, the Fund will not use its investments to enhance leverage or seek performance that is the multiple or inverse multiple of the Index. According to the Registration Statement, the Fund will invest in crypto assets through a fundamentally informed model-based process and will take an active view on specific crypto assets based on criteria such as fundamentals, valuation, and momentum, within a disciplined risk-based framework. The Shares are designed to provide investors with a means of obtaining price exposure to multiple crypto assets, as opposed to direct acquisition, holding, and trading of crypto assets on a peer-to-peer or other basis or via a crypto asset platform. The Shares are also intended to reduce the complexities and operational burdens associated with direct investment in these crypto assets, while seeking to generate returns that are higher than those of the Index and that reflect the investment exposure to the assets held by the Fund.

Custody of the Crypto Assets

The Crypto Custodian will keep custody of the Fund’s crypto assets. Except to the extent required to facilitate any staking activities (as further discussed below) or trading activities, the Crypto Custodian will safeguard the private key materials associated with the Fund’s crypto assets held by the Crypto Custodian. The Crypto Custodian’s policies, procedures, and controls for safekeeping must be designed to protect against theft, loss, and unauthorized and accidental use of the private keys.

The Sponsor represents that it will maintain ownership and control of the Fund’s crypto assets in a manner consistent with good delivery requirements for spot commodity transactions.

Staking

The Sponsor may, from time to time, stake a portion of the Fund’s crypto assets, as applicable, on behalf of the Fund through one or more trusted staking providers, which may include the Crypto Custodian or an affiliate of the Crypto Custodian (“Staking Providers”). However, the Sponsor will

pay interest to the holder nor afford the holder any governance rights, and do not represent any ownership interest in the issuer or (2) as otherwise permissible under federal law.

⁸ The term “net asset value” means an amount reflecting the current market value of the assets held by the Fund, less expenses and liabilities, used to periodically compute the current price for the purpose of creation and redemption of Fund Shares.

⁹ The Fund’s “Crypto Asset Holdings” means the portfolio of crypto assets, that, together with any stablecoins, cash, and cash equivalents, will form the basis for the Fund’s calculation of NAV at the end of each Business Day. A “Business Day” means any day other than a day when the Exchange is closed for regular trading.

not utilize any Staking Providers that are affiliates of the Sponsor. In consideration for any staking activity in which the Fund may engage, the Fund would receive certain staking rewards of crypto assets, which may be treated as income to the Fund for tax purposes.

To the extent the Sponsor determines to stake a portion of the Fund's crypto assets, the Sponsor expects to maintain sufficient liquidity in the Fund to satisfy redemptions. If the Fund engages in staking and has on a daily basis less than 85% of its crypto assets readily available,¹⁰ the Fund will have written liquidity risk policies and procedures that are reasonably designed to address the risk that it could not meet requests to redeem Shares issued by the Fund without significant dilution of remaining shareholders' interest in the Fund. Such policies and procedures will be periodically reviewed (with such review occurring no less frequently than annually) by the Fund and will address the following, as applicable:

- The Fund's investment strategy and liquidity of the Fund's crypto assets during normal and stressed conditions, including holdings in derivatives and whether the investment strategy is appropriate for effective and efficient arbitrage;
- Holdings of cash and cash equivalents, as well as borrowing arrangements and other funding sources; and
- Percentage and description of the Fund's crypto assets that are segregated, pledged, hypothecated, encumbered, or otherwise restricted or prevented from being liquidated, sold, transferred or assigned within one Business Day.

Valuation of Fund Assets and Determination of NAV

The NAV of the Fund will be equal to the total assets of the Fund, including but not limited to, all crypto assets, stablecoins, cash, and cash equivalents less total liabilities of the Fund, each determined by the Administrator as described herein. The NAV per Share is calculated by dividing the NAV of the Fund by the number of Shares currently outstanding.

In determining the Fund's NAV, the Administrator values each of the crypto assets and stablecoins held by the Fund based on a reference rate determined by the Administrator in its sole discretion (each a "Reference Rate" and, collectively, the "Reference Rates"). The Administrator will engage a third-party

vendor(s) to obtain a Reference Rate for each Eligible Asset.

Each Reference Rate will aggregate the trade flow of respective crypto assets on spot trading platforms, during an observation window between 3:00 p.m. and 4:00 p.m. E.T. into the U.S. dollar price of the respective crypto asset, at 4:00 p.m. E.T. If one or more Reference Rates is not available or the Administrator determines, in its sole discretion, that one or more Reference Rates is unreliable or unavailable, the Fund's holdings may be fair valued by the Administrator. Additionally, the Administrator will monitor for unusual prices and escalate to the Sponsor if detected. Notification of a material change to any Reference Rate will be made via a prospectus supplement, in the Fund's periodic Exchange Act reports, and/or on the Fund's website.

According to the Registration Statement, the Reference Rates are calculated based on transactions that take place on a crypto asset trading platform approved by the Reference Rate provider ("Relevant Transactions"). The methodology underlying each Reference Rate is as follows:

- All Relevant Transactions are added to a joint list, recording the trade price and size for each transaction.
- The joint list is partitioned into a number of equally-sized time intervals.
- For each partition separately, the volume-weighted median trade price is calculated from the trade prices and sizes of all Relevant Transactions (*i.e.*, across all relevant trading platforms).
- Each Reference Rate is then calculated as the equally weighted average of the volume-weighted medians of all partitions.

The Administrator believes that the Reference Rates reflect a reasonable valuation of the spot price of the Fund's crypto assets and that they are reasonably designed to be resistant to manipulation. For example, the Administrator believes that the Reference Rates' methodology mitigates the impact of crypto asset transactions conducted at outlier prices, large trades or clusters of trades transacted over a short period of time, and large trades at prices that deviate from the prevailing price on the Reference Rates.

The Administrator of the Fund will calculate the NAV once each Business Day, as of the close of trading on the Exchange or 4:00 p.m. E.T., whichever is earlier.

Background on Eligible Assets¹¹

As noted above, the Fund will only invest in Eligible Assets, which are not required to be identical to the Index Constituents. As of the date of this filing, based on its assessment of available data, the Sponsor considers the following to be Eligible Assets (ticker symbols in parentheses): bitcoin (BTC), ether (ETH), SOL (SOL), XRP (XRP), ada (ADA), AVAX (AVAX), litecoin (LTC), DOT (DOT), Dogecoin (DOGE), HBAR (HBAR), Bitcoin Cash (BCH), LINK (LINK), lumen (XLM), and Shiba Inu (SHIB). The Fund will disclose the crypto assets it considers to be Eligible Assets in its daily website holdings disclosures.

Bitcoin (BTC)

Bitcoin is a crypto asset that serves as the unit of account on an open-source, permissionless, decentralized, peer-to-peer computer network (known as the Bitcoin Network). It may be used to pay for goods and services, stored for future use, or converted to government-backed currency such as the U.S. dollar. Bitcoin is "stored" on a digital transaction ledger commonly known as a "blockchain." A blockchain is a distributed database that is continuously updated and reconciled among certain users and is protected by cryptography.

Transactions in bitcoin are broadcasted over the Bitcoin Network and registered in bundles called blocks, which are set to occur on average every 10 minutes and collectively track the full transaction history and ownership of bitcoins in circulation. Every block is cryptographically tied to its predecessor, creating a chain of blocks called the Bitcoin Blockchain. The Bitcoin Network introduces a cost for network participants to add new blocks of transactions to the Bitcoin Blockchain, which consists of creating a proof-of-work by solving a highly costly cryptographic problem by trial and error and broadcasting the obtained solution to other network participants for verification. Bitcoin is issued over time as a subsidy that rewards network participants responsible for generating proof-of-work and, thus, adding new blocks to the Bitcoin Blockchain. The creation of proof-of-work is referred to as bitcoin mining, and network participants engaging in the activity are called bitcoin miners.

The value of bitcoin depends on its supply (which is limited) as well as its demand across its trading venues. The supply of bitcoin follows a predefined

¹⁰ A crypto asset is deemed not readily available to meet redemption requests if it is segregated, pledged, hypothecated, encumbered, or otherwise restricted or prevented from being liquidated, sold, transferred, or assigned within one Business Day.

¹¹ The description of the Eligible Assets in this section is based on the Registration Statement.

issuance schedule since Bitcoin's conception. By design, the supply of bitcoin is intentionally limited to 21 million units. As of October 2025, there are approximately 19.93 million bitcoins in circulation.

Bitcoin is maintained on a decentralized, open source, peer-to-peer computer network, the Bitcoin Network. No single entity owns or operates the Bitcoin Network. The Bitcoin Network is accessed through software and governs bitcoin's creation and movement. The source code for the Bitcoin Network, often referred to as the Bitcoin Protocol, is open-source, and anyone can contribute to its development.

New bitcoins are created through a process called "mining." Miners use specialized computer software and hardware to solve a highly complex mathematical problem presented by the Bitcoin Protocol. The first miner to successfully solve the problem is permitted to add a block of transactions to the bitcoin blockchain. The new block is then confirmed through acceptance by a majority of users who maintain versions of the blockchain on their individual computers. Miners that successfully add a block to the bitcoin blockchain are automatically rewarded with a fixed amount of bitcoin for their effort plus any transaction fees paid by transferors whose transactions are recorded in the block. This reward system is how new bitcoin enters circulation and is the mechanism by which versions of the blockchain held by users on a decentralized network are kept in consensus.

Bitcoin futures and options trading occur on exchanges in the U.S. regulated by the CFTC. The market for CFTC-regulated trading of bitcoin derivatives has developed substantially. Ether (ETH)

Ethereum is a permissionless, decentralized and peer-to-peer computer network of nodes that enables developers to build and deploy the so-called smart contracts and decentralized apps ("DApps") on a global scale. Ether, the native crypto asset of the Ethereum Network, serves as a unit of account, allowing for peer-to-peer transactions and incentivizing network participants. Ethereum is an entire system, responsible for maintaining the ledger of ether ownership and enabling the transfer of ether among parties, as well as the components of the Ethereum system such as the Ethereum Network, the Ethereum Blockchain, the Ethereum Protocol and the Ethereum Clients (together, the "Ethereum System").

Transactions on Ethereum are broadcasted over the Ethereum Network and registered in blocks, which are set to occur every 12 seconds. Ethereum blocks collectively track the full transaction history, the accounts and balances of users and contracts in the Ethereum System, and other blockchain data that collectively are referred to as the state of Ethereum. Ethereum ensures that its state transition is deterministic, meaning that given the same initial state and set of transactions, all nodes in the Ethereum Network are able to compute the same final state.

Ethereum operates on a proof-of-stake consensus mechanism where users must lock a certain amount of ether to engage with transaction validation and code execution. In contrast to proof-of-work, in which miners expend hardware and electricity to become eligible to append new blocks to the blockchain, in proof-of-stake, users known as validators pledge capital denominated in ether as a "stake," providing a guarantee of action in good faith towards the honest operation of the network.

The initial creation of ether involved the issuance of 72.0 million tokens. Of these, 60.0 million ether (83.33% of the supply) were sold to the public in a crowd sale in 2014, raising approximately \$18 million. Another 6.0 million ether (8.33% of the supply) went to the Ethereum Foundation for operational costs, while 3.0 million ether each (4.17% of the supply) were distributed to developers who contributed to the network and members of the Ethereum Foundation for purchasing at the initial crowd sale price.

In October 2025, ether had a total circulating supply of about 121 million. In February 2025, of about 120 million circulating supply, approximately 72 million ether were pre-mined, 50.4 million ether were issued by miners before the switch to PoS, 2.3 million ether were issued to validators staking ether and 4.4 million ether were burned in base fees. There is no guarantee that the ether issuance policy will remain unchanged over time, and future modifications to monetary policy might create splits in the Ethereum community and lead to two or more conflicting Ethereum networks.

SOL (SOL)

Solana is a smart contract platform, enabling the creation of DApps such as decentralized finance ("DeFi"), digital collectibles, and blockchain games. Its system comprises the Solana Network, the Solana Blockchain, the Solana Protocol and Solana Clients. SOL is the native crypto asset for the Solana

Network. As of October 2025, SOL has a circulating supply of about 612 million tokens, and no fixed cap.

Solana uses Proof-of-Stake (PoS) for network consensus but integrates Proof-of-History (PoH) into its PoS mechanism to enable continuous block production. PoH ensures consistent block production, with each validator independently verifying the PoH sequence, eliminating the need for external time synchronization.

The Solana Blockchain relies on two types of globally distributed nodes: Validators and Remote Procedure Call (RPC) nodes. Validators are voting consensus nodes, while RPC nodes are non-voting nodes. Validators vote to determine the validity of transactions until consensus is reached. Once validated, the on-chain state changes are applied, and the transactions are recorded in the Solana ledger for permanent storage. The RPC node then sends the response back to the client application. Solana's governance relies on Solana Improvement Proposals (SIPs), which outline suggested network changes. Anyone can submit a SIP, but community support is crucial. Validators, developers, and stakeholders review proposals to reach consensus on updates that shape the blockchain's future.

On March 18, 2025, SOL futures became available for trading on CME, a CFTC-regulated marketplace.

XRP (XRP)

XRP Ledger is an open-source, decentralized blockchain created in 2012, designed to facilitate rapid and cost-effective global payments. Its system comprises the XRPL Blockchain, the XRPL Protocol and XRPL Clients. The native token of the XRP Ledger is XRP.

The XRP Ledger uses a unique consensus protocol that ensures all users can agree on the ledger's current state and the order of transactions. This protocol, known as the XRP Ledger Consensus Protocol, processes valid transactions without relying on a central operator, avoiding single points of failure. The XRP Ledger Consensus Protocol aims to agree on a set of transactions for the next ledger version, apply them in order, and confirm that all participants reach the same result. Once this process is complete, the ledger version is considered validated and final.

XRP tokens function both as a crypto asset and as a security measure to prevent spam and malicious activity. XRP has a burning mechanism where a small fee is levied on each transaction, and this fee is permanently removed

from the total supply. Accordingly, the total supply of XRP slightly differs from the maximum supply of 100 billion, with the current total at 99.98 billion.

XRP was created and distributed through a private sale, with Ripple Labs, the company behind the XRP Ledger, initially holding a significant portion of the total supply. The initial distribution of the pre-mined XRP tokens was allocated among Ripple, the company behind the XRP Ledger, its co-founders, and the core team. Out of the total supply of 100 billion tokens, Ripple received 80 billion, while the remaining 20 billion were assigned to the co-founders and core team. To maintain control over the supply, Ripple locked 55 billion of the 80 billion tokens it received. These locked tokens are periodically unlocked through monthly escrows. As of October 2025, approximately 60 billion XRP are in circulation.

Any changes affecting transaction processing or consensus must be approved by at least 80% of the network of validators. While Ripple Labs contributes to the network, its rights are the same as any other contributor. The XRP Ledger has over 150 validators, with more than 35 on the default Unique Node List (UNL), and Ripple operates only one of these nodes.

On May 20, 2025, XRP futures became available for trading on CME, a CFTC-regulated marketplace.

Ada (ADA)

Cardano is a blockchain platform designed for scalability, security, and sustainability, supporting smart contracts and decentralized applications. Its system comprises the Cardano Network, the Cardano Blockchain, the Cardano Protocol, and Cardano Clients. Ada is the native crypto asset of the Cardano system.

Cardano uses the Ouroboros PoS protocol to maintain its blockchain where each block contains transactions and data, cryptographically linked. The Cardano Protocol includes rules for transaction processing, block creation, and consensus. Cardano Clients run on distributed computers worldwide, which interact with the Network to maintain the Blockchain, validate transactions and execute smart contracts.

Ada is used to pay for transaction fees on the Network, as a peer-to-peer currency for value transfer, a unit of account with the ecosystem of applications, as the economic incentive for staking and participating in consensus, and within Cardano's governance model where ada holders can vote on proposals.

To participate in Ouroboros, ada holders can either operate staking pools and run Clients or delegate ada holdings to a staking pool. Over time, pool operators are selected to create blocks based on their share of the stake in the Network. Similarly to Bitcoin and Ethereum, network upgrades are managed through Cardano Improvement Proposals (CIPs).

Ada possesses a maximum supply cap of 45 billion coins, whose distribution included an initial coin offering, in which participants bought ada using other crypto assets such as bitcoin and ether prior to the network's genesis block, created on September 23, 2017. Approximately 31.1 billion ADA were initially distributed as follows: 648.2 million were assigned to the Cardano Foundation, 2.1 billion ada to EMURGO, 2.5 billion ada to IOHK, and 25.9 billion ada were sold to the public during the ICO. The remaining ada supply is distributed over time through staking rewards. When a stake pool successfully creates a block, it earns a reward to be shared among the pool's operators and delegators. The reward consists of a base reward, a fixed amount of ada awarded for creating a block, and fees paid by users whose transactions are included in the block. In October 2025, the circulating supply of ada was approximately 36 billion coins.

AVAX (AVAX)

Avalanche is a scalable, interoperable blockchain platform designed for high throughput and low latency, supporting DApps, custom blockchains called subnets, and asset creation. Its system comprises the Avalanche Network, the Avalanche Blockchain, the Avalanche Protocol, and Avalanche Clients. Avalanche utilizes a novel consensus protocol known as the Avalanche Consensus, a novel implementation of PoS based on repeated sub-sampling of validators to reach consensus quickly, offering speed and scalability over other PoS variants. The Avalanche Protocol governs how transactions are validated, blocks are created, and consensus is achieved across three primary blockchains. AVAX is the native crypto asset of the Avalanche system.

AVAX is used to pay for transaction fees on the Avalanche Network, as a peer-to-peer currency for value transfer, a unit of account with the ecosystem of applications, and as the economic incentive for staking and participating in consensus. AVAX has a maximum supply cap of 720 million tokens, and a portion of transaction fees is burned, introducing a deflationary mechanism that reduces the circulating supply over

time. In September 2020, 360 million coins were minted at network's genesis, and the other half AVAX tokens are minted over time as a reward to validators securing the system. The initial supply was distributed as follows: 72 million AVAX to the Avalanche Team, 72 million AVAX publicly sold in an ICO, 66.67 million AVAX to the Avalanche Foundation, 50.4 million AVAX to the community and development endowment, 36 million AVAX to strategic partnerships, 24.91 million AVAX privately sold, 18 million AVAX sold in a seed round, 18 million AVAX airdropped to early users of the ecosystem, and 2.32 million AVAX to the incentivized testnet program that took place prior to the Avalanche Network's launch.

The issuance of new AVAX is governed by dynamic parameters, which over time determine the future supply expansion rate subject to the asymptotic maximum cap of 720 million coins. As of October 2025, the circulating supply of AVAX was approximately 422 million coins.

Litecoin (LTC)

Litecoin is a decentralized, open-source blockchain designed for peer-to-peer transactions. It was created as an alternative to bitcoin with a block time of 2.5 minutes (rather than bitcoin's 10 minutes) and a different mining algorithm called Script, intended to be more memory-intensive, making it less susceptible to mining using application-specific integrated circuits (ASICs) and promoting a more decentralized block creation process. Its system comprises the Litecoin Network, the Litecoin Blockchain, the Litecoin Protocol, and Litecoin Clients. The native crypto asset of the Litecoin system is litecoin ("LTC").

The Litecoin Blockchain records all transactions in blocks, with each block linked to all its predecessors via a strong cryptographic tie created by its proof-of-work consensus mechanism. Clients allow users to interact with the Network to send value and miners to generate proof-of-work and append new blocks to the Blockchain, similar to bitcoin but tailored for Litecoin's specifications. Litecoin Network upgrades are managed through Litecoin Improvement Proposals (LIPs).

LTC is the native crypto asset of the Litecoin system, used in peer-to-peer transactions to pay for goods and services, stored for future use, or converted to government-backed currency such as the U.S. dollar. It has a maximum supply cap of 84 million coins. To make sure that the creation of blocks and thus the issuance of new

LTC occur on average every 2.5 minutes, the system also possesses a built-in difficulty adjustment that tunes the cost of generating a valid proof-of-work every interval of 2,016 blocks—approximately every 3.5 days—starting from its genesis block, which was mined on October 7, 2011. The supply of LTC follows a predefined issuance schedule since the Network's inception. In every multiple of 840,000 blocks following height 0 (840,000, 1,680,000, 2,520,000, etc.), the issuance of LTC per block is reduced in half. These events are also referred to as “halvings.” Litecoin's mining subsidy started at 50 LTC per mined block and remained constant between heights 0 and 839,999. The third and most recent halving happened on August 2, 2023 at height 2,520,000, setting the current subsidy per block to 6.25 LTC until height 3,359,999. In October 2025, the circulating supply of LTC was approximately 76 million coins.

DOT (DOT)

DOT is a crypto asset that is created and transmitted through the operations of the Polkadot Network, an online, decentralized, distributed computing platform that operates on a peer-to-peer basis. The Polkadot Network uses a heterogeneous multi-chain to ensure the secure transfer and authenticity of each DOT and hosts the public transaction ledger. This central chain is known as the Relay Chain, on which all DOT is recorded. The Relay Chain is a decentralized digital file, or ledger, that contains all the records of DOT and is stored in multiple copies globally on the computers of users of the Polkadot Network.

DOT is “stored” on a blockchain and is linked to a unique digital address, or wallet, that is associated with a public key and a private key. The public key is used to generate the address that is available to other users of the Polkadot Network. The address serves as the location to which DOT can be transferred and from which DOT can be sent. Ownership of DOT is established by recording on the Relay Chain the unique address and the amount of DOT held. The wallet thus holds the cryptographic keys associated with DOT, rather than the DOT itself.

All transactions on the Polkadot Network are recorded on the Relay Chain. Like other blockchains, the Polkadot Relay Chain can be thought of as a collective chain of digital signatures that reflect transaction history. The Relay Chain is downloaded and stored, in whole or in part, on the computers of each user of the Polkadot Network. The Relay Chain is public and accessible to

all, and includes a record of every DOT, every transaction in DOT in order and every public address on the Polkadot Network. Every computer on the Polkadot Network is a “node,” and collectively all of the nodes ensure that each new transaction in DOT adheres to certain rules before it is added to the Relay Chain.

Although there are size limits to each block, the Relay Chain is designed to represent a complete, transparent, secure and unbroken history of all the transactions that have occurred on the Polkadot Network. The Polkadot Network and associated software programs can view the Relay Chain to determine the exact balance, if any, of DOT associated with any public address listed on the Relay Chain.

In the October 2017 fundraiser of DOT, 10 million DOT were created. The following table reflects the current reported distribution of DOTs:

- 50% allocated to 2017 token sale investors.
- 5% allocated to the 2019 private sale investors.
- 3.4% allocated to 2020 token sale investors.
- 11.6% retained by the Web3 Foundation for future fundraising efforts.
- 30% allocated to the Web3 Foundation for operating expenses used to develop Polkadot.

Polkadot Network uses a “Nominated PoS” algorithm, in which “nominators” can delegate their tokens to trusted validators, giving them voting power in selecting validators while spreading security responsibilities across the network. There is no maximum amount of DOT. In October 2025, the circulating supply was 1.6 billion DOT.

Dogecoin (DOGE)

Dogecoin is a crypto asset that is created and transmitted through the operations of the peer-to-peer Dogecoin Network, a decentralized network of computers that operates on cryptographic protocols. The Dogecoin Blockchain is the decentralized ledger upon which Dogecoin transactions are processed and settled, serving as the underlying technology of the Dogecoin Network. No single entity owns or operates the Dogecoin Blockchain, the infrastructure of which is collectively maintained by a decentralized user base.

The Dogecoin Network allows people to exchange tokens of value, Dogecoin, which are recorded on the Dogecoin Blockchain. The Dogecoin Network is based on a shared public ledger, the Dogecoin Blockchain, similar to the Bitcoin network. However, the Dogecoin Network differentiates itself from other

crypto asset networks in that its stated primary function is community-driven and widely used for tipping and microtransactions, rather than serving as a store of value. The Dogecoin Network is designed to be a fast and accessible peer-to-peer payment system.

Transactions are validated on the Dogecoin Blockchain by a network of independent nodes. These nodes participate in securing and updating the ledger through a proof-of-work mechanism. Any participant can run a node to validate transactions and contribute to the health and integrity of the network. Unlike permissioned systems, the Dogecoin Blockchain operates in a fully decentralized and permissionless manner, allowing anyone to join and participate in the network without requiring approval or relying on trusted entities. The process begins when a user submits a transaction to the Dogecoin Network. The submitted transaction is broadcast to nodes within the network. Miners, who act as validators, then group transactions into blocks and compete to solve a computational puzzle as part of the proof-of-work process. The first miner to successfully solve the puzzle adds their block of transactions to the blockchain. Once a block is added, it is shared with all nodes in the network, which validate the new block and ensure that it conforms to the blockchain's rules. This decentralized process ensures the accuracy and security of the Dogecoin Blockchain.

The supply of Dogecoin is unlimited. As of October 2025, there were about 151 billion Dogecoins in circulating supply.

HBAR (HBAR)

The Hedera Network is a public distributed ledger technology network that enables people to interact and transact online efficiently and securely without the need for third-party companies, which often collect and sell their users' personal information. The purpose of the Hedera Network is to provide a stable, trustworthy network for a wide variety of decentralized, enterprise-grade applications. Although the primary purpose of the Hedera Network is not to operate a payments system or store of value, like most public DLT networks, the Hedera Network requires a crypto asset to properly operate and incentivize consensus and behavior on the DLT network. HBAR is the native crypto asset of the Hedera Network. HBAR are used to power decentralized applications, build peer-to-peer transactional models, and protect the network from malicious actors.

The Hedera Network is built on the hashgraph distributed consensus algorithm, invented by Dr. Leemon Baird and subsequently patented by Swirlds, Inc. in 2016. Swirlds has granted to Hedera an exclusive non-transferable, perpetual right and license to using hashgraph technology for the limited and sole purpose of making the Hedera Network. The hashgraph data structure and consensus algorithm provides a novel platform for distributed consensus.

Hashgraphs also package transactions into blocks, but unlike on a blockchain, all hashgraph blocks are added to the distributed ledger, regardless of their order or circumstance—none are discarded. The hashgraphs are all used to create a more complete picture of the network's transactional data. The resulting structure is called a Directed Acyclic Graph ("DAG"). One of the primary advantages of DAGs over blockchains is that they can reduce the data size per transaction, thereby lowering costs, increasing speed, and ultimately achieving higher levels of scalability.

To achieve consensus on the network's transactional data, hashgraph calculates a fair order of transactions in a decentralized environment. Hashgraph uses "gossip about gossip" and virtual voting in order to bring the network to consensus on the timestamp of any event with efficiency of bandwidth usage without centralizing around any entity or group of entities. Nodes continuously communicate all the information they hold about transactions to other nodes at random via gossip protocol. Every time two nodes come in sync, each node marks the completion of the sync with an "event." An event is a data structure that is stored in the network's memory and comprises a timestamp, transactions, two hashes of the last of each node's events, and a cryptographic signature. Hashgraph calculates timestamps via automated virtual voting such that consensus is collectively arrived at by all nodes.

The Hedera Network is governed by the Hedera Governing Council ("Hedera Council"), a rotating group of global organizations that span across multiple industries and geographies. The primary responsibilities of Hedera Council members are to: (i) participate in the governance of the Hedera Network; and (ii) host and maintain a node on the Hedera Network. Hedera Council members contribute their expertise and experience in Hedera Council deliberations and decision-making relating to software updates, Hedera Treasury management, network pricing,

regulatory compliance, and other key governance matters.

The Hedera Network was launched in August 2018. At that time, the network's total fixed supply of HBAR of 50 billion HBAR was minted and placed into a Hedera Treasury account. The Hedera Treasury consists of multiple cryptographically secure, multi-signature accounts. HBAR can be transferred out of a Hedera Treasury account only after a transaction is cryptographically signed by a majority of the Hedera Council members. This ensures that control over the network's crypto assets remains decentralized and vested in large, trustworthy entities. Hedera's HBAR release plan calls for a slow, measured release of HBAR out of the Hedera Treasury. Hedera's strategy behind this schedule is to release HBAR from the Hedera Treasury such that the growth of circulating supply is commensurate with the adoption and use of the Hedera Network.

Hedera's strategy regarding the number of HBAR in circulation may change depending on several factors, including (but not limited to) accelerated or diminished demand for services on the network, network security considerations, efforts to provide incentives or support to developers and others who will encourage use of the network, and as may be needed based on regulatory considerations. As of October 2025, the circulating supply was about 42 billion HBAR.

Bitcoin Cash (BCH)

Bitcoin Cash (BCH) is a crypto asset created and transmitted through the operations of the peer-to-peer Bitcoin Cash Network. BCH has a maximum supply of 21 million coins and a circulating supply of approximately 20 million coins as of October 2025. In July 2017, bitcoin miners implemented a software upgrade known as BIP 91, which activated the Segregated Witness (SegWit) upgrade at block 477,120. SegWit was sought to enable second-layer solutions on bitcoin, such as the Lightning Network. Several developers, miners and other participants on the Bitcoin blockchain opposed the proposed SegWit upgrades designed to increase bitcoin's capacity; these stakeholders pushed forward alternative plans which would increase the block size limit to eight megabytes through a hard fork.

BCH was created as a result of a fork of the Bitcoin blockchain on August 1, 2017, at block 478,559. Up to the previous block (478,558), the bitcoin and Bitcoin Cash blockchains were identical. This means that anyone who

owned one bitcoin at the time of the fork automatically owned one unit of Bitcoin Cash. The technical difference between Bitcoin Cash and bitcoin at the time of the fork is that Bitcoin Cash supports larger block sizes. This allows the Bitcoin Cash blockchain to process more transactions per second compared to bitcoin.

LINK (LINK)

LINK is an ERC-677 token that serves as the native digital currency for the Chainlink Network, a decentralized "oracle" platform that is an application built on the Ethereum Network. LINK relies on the Ethereum Network for key functionalities such as storage, transfer and usage.

LINK was created by Chainlink Labs, formerly known as SmartContract.com, a company founded in 2014 to create a bridge between external data and public blockchains. In 2017, Chainlink Labs introduced the Chainlink Network, a decentralized network aimed at linking real world data and public blockchains by connecting smart contracts to off-chain data for markets, events, and data. The Chainlink Network consists of three main blockchain components: oracle selection, data reporting, and result aggregation.

The LINK token is used to pay Chainlink node operators for oracle services. For a smart contract on Ethereum to use a Chainlink node, it will have to pay the node using LINK. Chainlink nodes may also stake LINK as collateral as a way of insuring the data delivery service. This staking functionality is optional.

The initial funding for Chainlink occurred in September 2017 when Chainlink Labs raised \$32 million by selling 350 million LINK to the public. In total, one billion LINK were issued. As of October 2025, the circulating supply was about 678 million.

Lumen (XLM)

Lumen is the native token of the Stellar Network. The Stellar Network was created in 2014 by a team of scientists, advisers, and engineers of the Stellar Development Foundation ("SDF"). The Stellar Ledger uses a consensus mechanism called the Stellar Consensus Protocol which is an implementation of the Federated Byzantine Agreement pioneered by Ripple, which is similar to proof-of-stake, but does not include staking rewards or incentives. Instead, the Federated Byzantine Agreement is a consensus mechanism where nodes independently decide which other nodes to trust for information. Lumens transactions are resolved around every

six seconds, which is faster than Bitcoin's block production, which are resolved around every 10 minutes. SDF oversaw the creation of all of the XLM in existence and, as part of its custodial mandate, continues to oversee how the vast majority of XLM are distributed. Initially, 100 billion XLM were created by SDF and were required to be distributed as follows: (i) 50% to individuals, (ii) 25% to partners such as businesses, governments, institutions, or nonprofit organizations that contribute to the growth and adoption of the Stellar Network, (iii) 19% to Bitcoin holders and 1% to XRP holders in giveaways conducted in October 2016 and August 2017 and (iv) 5% reserved for SDF operational expenses.

No further lumen could be created or distributed according to the Stellar protocol, aside from supply increases by a fixed inflation rate of 1% per year, which ceased pursuant to a Stellar community vote in October 2019. In November 2019, SDF removed, or "burned," approximately 55 billion of the approximately 105 billion of lumen total supply. As of October 2025, there is a total of about 50 billion lumens in existence.

According to SDF, as of October 2025, SDF held approximately 30 billion lumen (more than 50% of the supply) to develop and promote the growth of the Stellar network and the expectation is that those lumens will enter the open markets over the next few years. The remaining 20 billion lumen are in the open market.

Shiba Inu (SHIB)

Shiba Inu (SHIB) is a crypto asset created in August 2020 by an anonymous entity called "Ryoshi." SHIB is an Ethereum-based crypto asset considered by many to be a meme-inspired project based on the Dogecoin meme featuring the Shiba Inu dog as its mascot. To improve efficiency, the community developed Shibarium, a Layer-2 blockchain built on Ethereum, designed to reduce transaction costs and increase throughput. SHIB is a deflationary token designed to be used as a medium of exchange and store of value. SHIB has a total supply of 1,000,000,000,000,000 (1 quadrillion) tokens. SHIB is the most widely available of four principal types of tokens that form part of the SHIB ecosystem.

The SHIB ecosystem supports projects such as an non-fungible token art incubator and the development of a decentralized exchange called ShibaSwap, designed to boost the utility of the SHIB tokens. Users can trade tokens, deposit in liquidity pools, stake

their coins, and vote on ShibaSwap governance proposals. These functions are handled by smart contracts on the Ethereum blockchain, which allows users to trade any supported ERC-20 token directly with other users.

Users who add their tokens to a liquidity pool are termed to be "digging" for BONE token rewards. "Diggers" create ShibaSwap Liquidity Provider (SSLP) tokens and deposit them into a liquidity pool. These tokens represent each digger's share in the trading pool and can be used to claim BONE rewards. The more liquidity a digger provides and the longer SSLP tokens are left in the pool, the more rewards the digger can potentially earn. This incentivizes users to contribute to ShibaSwap's liquidity and decentralization, which helps stabilize the tokens' prices and ensure smooth trading.

"Bury" is ShibaSwap's term for staking, another key feature of the platform. "Buried" tokens are temporarily removing them from circulation. In return for this, stakers earn rewards in the form of additional tokens. On ShibaSwap, SHIB, LEASH, and BONE tokens can all be "buried." Once buried, these tokens earn returns paid out in a wrapped version of the staked tokens.

As of October 2025, SHIB has a circulating supply of about 589 trillion.

The Structure and Operation of the Fund Protects Investors

The Sponsor believes the structure and operation of the Fund are designed to mitigate fraudulent and manipulative acts and practices and to protect investors and the public interest. The Sponsor accordingly believes the Commission should approve the listing and trading of Shares of the Fund.

The Commission has historically approved or disapproved exchange filings to list and trade series of Trust Issued Receipts, including spot, Commodity-Based Trust Shares, on the basis of whether the listing exchange has in place a CSSA with a regulated market of significant size related to the underlying commodity to be held.¹² The

¹² See Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (SR-BatsBZX-2016-30) (Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, to List and Trade Shares of the Winklevoss Bitcoin Trust) ("Winklevoss Order"). In the Winklevoss Order, the Commission set forth both the importance and definition of a surveilled, regulated market of significant size, explaining that, for approved commodity-trust ETPs, "there has been in every case at least one significant, regulated market for trading futures on the underlying commodity—whether gold, silver, platinum,

Commission has since approved the listing and trading of shares of spot bitcoin exchange-traded products ("Spot Bitcoin ETPs") and spot ether exchange-traded products ("Spot Ether ETPs"), finding that there were sufficient "other means" of preventing fraud and manipulation sufficient to satisfy the requirements of Section 6(b)(5) of the Exchange Act.¹³ In each of the Spot Bitcoin ETP Approval Order and Spot Ether Approval Order, the Commission concluded, through a correlation analysis, that fraud or manipulation that impacts prices in spot bitcoin markets or spot ether markets would likely similarly impact CME bitcoin futures prices and CME ether futures prices, respectively.¹⁴ The Commission further found that, because the CME's surveillance can assist in detecting those impacts on CME bitcoin futures prices and CME ether futures prices, a listing exchange's CSSA with the CME can be reasonably expected to assist in surveilling for fraudulent and manipulative acts and practices in the context of the Spot Bitcoin ETPs and Spot Ether ETPs.¹⁵

The Commission has also approved the listing and trading of shares of exchange-traded products that hold both spot bitcoin and spot ether in proportion to their market capitalizations (the "Spot Bitcoin/Ether ETPs").¹⁶ In approving the Spot Bitcoin/

palladium, or copper—and the ETP listing exchange has entered into surveillance-sharing agreements with, or held Intermarket Surveillance Group membership in common with, that market." Winklevoss Order, 83 FR at 37594.

¹³ See Securities Exchange Act Release No. 34-99306 (January 10, 2024), 89 FR 3008 (January 17, 2024) (SR-NYSEARCA-2021-90; SR-NYSEARCA-2023-44; SR-NYSEARCA-2023-58; SR-NASDAQ-2023-016; SR-NASDAQ-2023-019; SR-CboeBZX-2023028; SR-CboeBZX-2023-038; SR-CboeBZX-2023-040; SR-CboeBZX-2023-042; SR-CboeBZX-2023-044; SR-CboeBZX-2023-072) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units) (the "Spot Bitcoin ETP Approval Order"); Securities Exchange Act Release No. 100224 (May 23, 2024), 89 FR 46937 (May 30, 2024) (SR-NYSEARCA-2023-70; SR-NYSEARCA-2024-31; SR-NASDAQ-2023-045; SR-CboeBZX-2023-069; SR-CboeBZX-2023-070; SR-CboeBZX-2023-087; SR-CboeBZX-2023-095; SR-CboeBZX-2024-018) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to List and Trade Shares of Ether-Based Exchange-Traded Products) (the "Spot Ether ETP Approval Order").

¹⁴ See Spot Bitcoin ETP Approval Order, 89 FR at 3010; Spot Ether ETP Approval Order, 89 FR at 46938.

¹⁵ See Spot Bitcoin ETP Approval Order, 89 FR at 3010; Spot Ether ETP Approval Order, 89 FR at 46938-39.

¹⁶ See Securities Exchange Act Release No. 101998 (December 19, 2024), 89 FR 106707 (December 30, 2024) (SR-NASDAQ-2024-028; SR-CboeBZX-2024-091) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment

Ether ETPs, the Commission similarly found, based on the continued consistent correlation between the spot bitcoin market and the CME bitcoin futures market and between the spot ether market and the CME ether futures market, that a listing exchange's CSSA with the CME can be reasonably expected to assist in surveilling for fraudulent and manipulative acts and practices in the context of the Spot Bitcoin/Ether ETPs.¹⁷

Most recently, the Commission approved generic listing standards for the listing and trading of shares of Commodity-Based Trust Shares that meet certain requirements.¹⁸ Among other requirements, the generic listing standards provide that a commodity or commodity underlying commodity-based assets held by a trust issuing Commodity-Based Trust Shares is an eligible holding of the trust if it meets at least one of the following criteria:

- On an initial and continuing basis, the commodity trades on a market that is an ISG member, provided that the Exchange may obtain information about trading in such commodity from the ISG member;
- On an initial and continuing basis, the commodity underlies a futures contract that has been made available to trade on a DCM for at least six months, provided that the Exchange has a CSSA, whether directly or through common membership in ISG, with such DCM; or
- On an initial basis, an ETF designed to provide economic exposure of no less than 40% of its NAV to the commodity lists and trades on a national securities exchange.¹⁹

In approving the generic listing standards, the Commission found that these eligibility criteria for trust holdings would facilitate information sharing and help to ensure the availability of information necessary to aid in the detection and deterrence of potential fraud and manipulation with respect to a commodity or commodity

underlying a commodity-based asset, and that the availability of such information can be reasonably expected to assist a listing exchange in its efforts to surveil for fraud and manipulation that may impact the Commodity-Based Trust Shares.²⁰

The Sponsor believes that, for reasons similar to those set forth in the Spot Bitcoin ETP Approval Order, Spot Ether ETP Approval Order, Spot Bitcoin/Ether ETP Approval Order, and Generic Listing Standards Approval Order, listing and trading Shares of the Fund would be consistent with the requirements of the Act. As noted above, the Fund may only hold Eligible Assets, which must meet the eligibility criteria described above in the opinion of the Sponsor. Those eligibility criteria are substantially similar to the eligibility criteria set forth in Rule 8.201–E(d)(1) (Generic) for commodities or commodities underlying commodity-based assets held by a trust issuing Commodity-Based Trust Shares. The universe of Eligible Assets, as of the date of this filing, includes commodities that, in the opinion of the Sponsor, meet, or will meet by the time the Shares begin trading on the Exchange, the eligibility criteria set forth in Rules 8.201–E(d)(1)(ii) (Generic) (relating to commodities underlying futures contracts that have been available to trade for at least six months on a DCM with which the Exchange has a CSSA) and/or 8.201–E(d)(1)(iii) (Generic) (relating to commodities for which an ETF designed to provide economic exposure of no less than 40% of its net asset value to that commodity lists and trades on a national securities exchange). Accordingly, the Sponsor believes that the Exchange's ability to obtain information regarding trading in futures on Eligible Assets from DCMs with which the Exchange has a CSSA, whether directly or via common ISG membership, would assist the Exchange in detecting potential fraud or manipulation with respect to trading in the Shares. In addition, to the extent Eligible Assets are commodities for which there is an ETF that provides economic exposure of at least 40% of its net asset value to the commodity, the Exchange similarly would be able to obtain information with respect to those listed and traded ETFs that have exposure to the same underlying commodity from the listing exchange (which, as a national securities exchange, would be an ISG member) to facilitate information sharing and help ensure the availability of information

necessary to aid in the detection and deterrence of potential manipulation.

Creation and Redemption of Shares

The Fund will create and redeem Shares on a continuous basis only in aggregations of 10,000 Shares ("Creation Units"). Only Authorized Participants, which are registered broker-dealers who have entered into written agreements with the Distributor and the Administrator, can place orders to purchase or redeem Creation Units in exchange for cash.

The Authorized Participants will deliver only cash to create Shares and will receive only cash when redeeming Shares. The Fund may publish a basket of pro rata or non-pro rata holdings on a daily basis for informational purposes only. Authorized Participants will not directly or indirectly purchase, hold, deliver, or receive crypto assets as part of the creation or redemption process or otherwise direct the Fund or a third-party with respect to purchasing, holding, delivering, or receiving crypto assets as part of the creation or redemption process.

The Sponsor and the Fund will engage in crypto asset transactions for converting cash, stablecoins, or crypto assets into other crypto assets (in association with purchase orders) and the Fund's crypto assets into cash (in association with redemption orders). The Fund will conduct its crypto asset transactions by choosing, in its sole discretion, either to trade directly with third parties, who are not registered broker-dealers, pursuant to written agreements between such counterparties (each a "Crypto Trading Counterparty") and the Fund. The Sponsor and the Fund expect to conduct these transactions by trading directly with Crypto Trading Counterparties.

A Crypto Trading Counterparty may be an affiliate of an Authorized Participant. Crypto Trading Counterparties may be added at any time, subject to the discretion of the Sponsor. The Sponsor and/or the Fund are solely responsible for selecting the third party to deliver or receive crypto assets. Further, the third party will not be acting as an agent of the Authorized Participant with respect to the delivery or receipt of the crypto assets to the Fund or acting at the direction of the Authorized Participant. The third party will be unaffiliated with the Fund, Sponsor, or Administrator.

Creation Procedures

For a creation order, the Authorized Participant will be required to submit the purchase order by a time determined by the Sponsor, or the close of regular

No. 1, To List and Trade Shares of the Hashdex Nasdaq Crypto Index US ETF and Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Franklin Crypto Index ETF, a Series of the Franklin Crypto Trust) (the "Spot Bitcoin/Ether ETP Approval Order").

¹⁷ See Spot Bitcoin/Ether ETP Approval Order, 89 FR at 106708.

¹⁸ See Securities Exchange Act Release No. 103995 (September 17, 2025), 90 FR 45414 (September 22, 2025) (SR–NASDAQ–2025–056; SR–CboeBZX–2025–104; SRNYSEARCA–2025–54) (Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to Adopt Generic Listing Standards for Commodity-Based Trust Shares) ("Generic Listing Standards Approval Order").

¹⁹ See, e.g., NYSE Arca Rules 8.201–E(d)(1)(i)–(iii) (Generic).

²⁰ See Generic Listing Standards Approval Order, 90 FR at 45418–19.

trading on the Exchange, whichever is earlier (the “Order Cutoff Time”). The Authorized Participant must submit a purchase order indicating the number of Creation Units it intends to acquire. The Sponsor will acknowledge the purchase order and the date of acknowledgement will determine the “Estimated Cash Amount,” which is equivalent in value to the quantity of the Fund’s crypto assets and other portfolio assets (together, the “Crypto Asset Basket”) and excludes Slippage²¹ and transaction fees, that the Authorized Participant needs to deposit.

On the date of a creation order, the Fund will enter into a transaction by choosing, in its sole discretion, to trade directly with a Crypto Trading Counterparty to buy crypto assets in exchange for the cash proceeds from such creation order. For settlement of a creation order, the Fund delivers Shares to the Authorized Participant in exchange for cash received from the Authorized Participant. Meanwhile, the Crypto Trading Counterparty delivers the required crypto assets in exchange for cash.

The Administrator will make available on each Business Day, before the start of trading on the Exchange, the “Crypto Asset Basket” for that Business Day. Authorized Participants may use the Crypto Asset Basket as guidance regarding the “Estimated Cash Amount” that they may expect to have to deposit with the Administrator in respect of accepted purchase orders placed on such Business Day.

To the extent the price for buying the crypto assets is higher than the price utilized in calculating the NAV, the Authorized Participant is responsible for paying the Slippage. In the case the price for buying the crypto assets is lower than the price utilized in calculating the NAV, the Authorized Participant shall keep the Slippage.

The “Total Cash Amount” is the cash equivalent value of the Crypto Asset Basket, plus Slippage and transaction fees. The Total Cash Amount owed by the Authorized Participant will be determined after the Fund’s NAV is struck and the Fund’s crypto asset transactions have been confirmed. The calculation of the Total Cash Amount necessary for the creation of a Creation Unit changes from day to day. Each day that the Exchange is open, the computation is made by the Administrator as promptly as

practicable after a time determined by the Sponsor.

Redemption Procedures

Authorized Participants, acting on authority of the registered holder of Shares, may surrender Creation Units in exchange for the corresponding Total Cash Amount. For a redemption, the Authorized Participant will be required to submit a redemption order by an Order Cutoff Time. The Authorized Participant must submit a redemption order indicating the number of Creation Units it intends to redeem. The Sponsor will acknowledge the redemption order and the date of acknowledgement will determine the Estimated Cash Amount that the Authorized Participant expects to receive in connection with the crypto asset portfolio that the Fund needs to sell to the Crypto Trading Counterparty.

On the date of the redemption order, the Fund will enter into a transaction by choosing, in its sole discretion, to trade directly with a Crypto Trading Counterparty to sell crypto assets in exchange for the cash proceeds to fulfill the redemption order. For settlement of a redemption, the Fund delivers cash to the Authorized Participant in exchange for shares received from the Authorized Participant. Meanwhile, the Crypto Trading Counterparty delivers the required cash in exchange for crypto assets.

Availability of Information

The Fund’s website, which will be publicly available at no charge, will include quantitative information on a per Share basis updated on a daily basis, including (i) the current NAV per Share daily and the prior Business Day’s NAV per Share and the reported closing price of the Shares; (ii) the mid-point of the bid-ask price²² as of the time the NAV per Share is calculated (“Bid-Ask Price”) and a calculation of the premium or discount of such price against such NAV per Share; and (iii) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid-Ask Price against the NAV per Share, within appropriate ranges, for each of the four previous calendar quarters (or for as long as the Fund has been trading as an ETP if shorter). In addition, on each Business Day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose the following information on its

website with respect to the Crypto Asset Holdings:

- For each of the Fund’s Crypto Asset Holdings, to the extent applicable: (i) ticker symbol; (ii) identifier; (iii) description of the holding; (iv) the quantity of each asset; and (v) percentage weighting;
- The Fund’s current NAV per Share, market price,²³ and premium or discount,²⁴ each as of the end of the prior Business Day;
- A table showing the number of days the Fund’s Shares traded at a premium or discount during the most recently completed calendar year and the most recently completed calendar quarters since that year (or the life of the Fund, if shorter);
- A line graph showing the Fund Shares’ premiums or discounts for the most recently completed calendar year and the most recently completed calendar quarters since that year (or the life of the Fund, if shorter); and
- The Fund Shares’ median bid-ask spread, expressed as a percentage rounded to the nearest hundredth, computed by: (i) identifying the Fund Shares’ national best bid and national best offer as of the end of each 10 second interval during each trading day of the last 30 calendar days; (ii) dividing the difference between each such bid and offer by the midpoint of the national best bid and national best offer; and (iii) identifying the median of those values.

The Fund’s website will also provide a form of the prospectus for the Fund that may be downloaded.

The NAV per Share for the Fund will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (the “CTA”).

The Sponsor will engage an independent calculator to calculate and disseminate an intraday trust value (“ITV”). One or more major market data vendors will provide an ITV updated every 15 seconds, as calculated by the

²³ The term “market price” means: (i) the official closing price of a Fund Share; or (ii) if it more accurately reflects the market value of a Fund Share at the time as of which the Fund calculates current net asset value per share, the price that is the midpoint between the national best bid and national best offer as of that time.

²⁴ The term “premium or discount” means the positive or negative difference between the market price of a Fund Share at the time as of which the current net asset value is calculated and the Fund’s current net asset value per share, expressed as a percentage of the Fund Share’s current net asset value per share.

²¹ “Slippage” is the difference in the dollar cost of the Digital Assets’ price utilized in calculating the NAV per Share on the creation (or redemption) order date and the price at which the Fund acquires (or sells) the Digital Assets.

²² The bid-ask price of the Fund is determined using the highest bid and lowest offer on the Consolidated Tape as of the time of calculation of the closing day NAV.

Exchange or a third-party financial data provider during the Exchange's Core Trading Session (9:30 a.m. to 4:00 p.m. E.T.). The ITV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during the NYSE Arca Core Trading Session to reflect changes in the value of the Fund's NAV per Share during the trading day.

The ITV's dissemination during the Core Trading Session should not be viewed as an actual real time update of the NAV per Share, which will be calculated only once at the end of each trading day. The ITV will be widely disseminated every 15 seconds during the Core Trading Session by one or more major market data vendors. In addition, the ITV will be available through online information services.

The NAV per Share for the Fund will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time.

Quotation, last sale information, real-time price, volume data, and spot prices for the Fund's crypto assets will be widely disseminated through major market data vendors by subscription. On each Business Day, the Administrator will publish the Fund's NAV, and the NAV per Share on the Fund's website as soon as practicable after its determination. If the NAV and NAV per Share have been calculated using a price other than any Reference Rates, the publication on the Fund's website will note the valuation methodology used and the price resulting from such calculation.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services.

Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m. E.T., in accordance with NYSE Arca Rule 7.34-E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6-E, the minimum price variation ("MPV") for quoting and entry of orders in equity securities

traded on the NYSE Arca Marketplace is \$0.01, with the exception of securities that are priced less than \$1.00, for which the MPV for order entry is \$0.0001.

The Shares will be required to conform to the initial and continued listing criteria under NYSE Arca Rule 8.201-E(e) (Non-Generic). The trading of the Shares will be subject to NYSE Arca Rule 8.201-E(g) (Non-Generic), which sets forth certain restrictions on Equity Trading Permit Holders ("ETP Holders") acting as registered market makers ("Market Makers") in Commodity-Based Trust Shares to facilitate surveillance. The Exchange represents that, for initial and continued listing, the Fund will be required, to the extent necessary, to comply with Rule 10A-3²⁵ under the Act, as provided by NYSE Arca Rule 5.3-E. A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

The Exchange will obtain a representation from the Sponsor that the NAV per Share will be calculated daily and that the NAV and the Crypto Asset Holdings will be made available to all market participants at the same time on a daily basis.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.²⁶ Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12-E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (a) the extent to which trading is not occurring in the Crypto Asset Holdings composing the portfolio; or (b) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.

The Exchange may halt trading during the day if it becomes aware that there has been an interruption to the dissemination of the ITV. If the interruption to the dissemination of the ITV persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the NYSE Arca Core Trading Session on the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV per Share is not disseminated to all market participants at the same time, it

will halt trading in the Shares until such time as the NAV per Share is available to all market participants.

Surveillance

The Exchange represents that trading in the Shares of the Fund on the Exchange will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority ("FINRA") on behalf of the Exchange, which are designed to detect potential violations of Exchange rules and applicable federal securities laws with respect to the Shares of the Fund trading on the Exchange.²⁷ The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws with respect to the Shares of the Fund trading on the Exchange.

The existing surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity with respect to the Shares of the Fund. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate regarding trading in the Shares with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and crypto asset derivatives from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and crypto asset derivatives from markets and other entities with which the Exchange has in place a CSSA.²⁸ The Exchange is also able to obtain information from ETP Holders acting as registered Market Makers regarding their trading (as principal or agent) in the Shares and any underlying crypto assets, crypto asset futures contracts, options on crypto assets, or any other crypto asset derivative.

²⁷ FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

²⁸ For a list of the current members of ISG, see www.isgportal.org.

²⁵ 17 CFR 240.10A-3.

²⁶ See NYSE Arca Rule 7.12-E.

In addition, under NYSE Arca Rule 8.201–E(g) (Non-Generic), an ETP Holder acting as a registered Market Maker in the Shares is required to provide the Exchange with information relating to its accounts for trading in any underlying commodity, related futures or options on futures or any other related derivatives. Commentary .04 of NYSE Arca Rule 11.3–E requires an ETP Holder acting as a registered Market Maker, and its affiliates, in the Shares to establish, maintain and enforce written policies and procedures reasonably designed to prevent the misuse of any material nonpublic information with respect to such products, any components of the related products, any physical asset or commodity underlying the product, applicable currencies, underlying indexes, related futures or options on futures, and any related derivative instruments (including the Shares). As a general matter, the Exchange has regulatory jurisdiction over its ETP Holders and their associated persons, which include any person or entity controlling an ETP Holder. To the extent the Exchange may be found to lack jurisdiction over a subsidiary or affiliate of an ETP Holder that does business only in commodities or futures contracts and that subsidiary or affiliate is a member of another regulatory organization, the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations to the extent the Exchange has such an agreement with that regulatory organization.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The Sponsor has represented to the Exchange that it will advise the Exchange if the Fund ceases to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Exchange becomes aware that the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

Information Bulletin

At or prior to the commencement of trading, the Exchange will inform its ETP Holders in an “Information Bulletin” of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) the procedures for creations of Shares; (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) information regarding how the NAV and ITV are disseminated; (4) the possibility that trading spreads and the resulting premium or discount on the Shares may widen during the Early and Late Trading Sessions, when an updated ITV will not be calculated or publicly disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information. The Exchange notes that investors purchasing Shares directly from the Fund will receive a prospectus.

In addition, the Information Bulletin will reference that the Fund is subject to various fees and expenses as described in the Registration Statement. The Information Bulletin will disclose that information about the Shares of the Fund is publicly available on the Fund’s website.

The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)²⁹ that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of, a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.201–E(e) (Non-Generic). The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading

sessions on the Exchange and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and crypto asset derivatives from such markets. In addition, the Exchange may obtain information regarding trading in the Shares and crypto asset derivatives from markets that are members of ISG or with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Rule 8.201–E(g) (Non-Generic), the Exchange is able to obtain information regarding Market Maker accounts for trading in the Shares and the underlying crypto assets or any crypto asset derivative through ETP Holders acting as registered Market Makers, in connection with such ETP Holders’ proprietary trades which they effect on any relevant market.

The proposed rule change is also designed to prevent fraudulent and manipulative acts and practices because the Fund will hold only Eligible Assets, which are crypto assets that meet eligibility criteria substantially similar to the generic listing standards in NYSE Arca Rule 8.201–E(d)(1) (Generic) for commodities or commodities underlying commodity-based assets held by trusts issuing Commodity-Based Trust Shares. The Exchange believes that, for reasons similar to those set forth in the Spot Bitcoin ETP Approval Order, Spot Ether ETP Approval Order, Spot Bitcoin/Ether ETP Approval Order, and Generic Listing Standards Approval Order, listing and trading Shares of the Fund would be consistent with the requirements of the Act because the universe of Eligible Assets, as of the date of this filing or by the time Shares begin trading on the Exchange, includes commodities that meet the eligibility criteria set forth in Rules 8.201–E(d)(1)(ii) and/or (iii) (Generic), such that the Exchange would be able to obtain information from DCMs with which the Exchange has a CSSA or from national securities exchanges that are ISG members relating to crypto assets held by the Fund, which would assist the Exchange in detecting potential fraud or manipulation with respect to trading in the Shares.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of crypto asset price and market information available

²⁹ 15 U.S.C. 78f(b)(5).

on public websites and through professional and subscription services. Investors may obtain, on a 24-hour basis, crypto asset pricing information based on the spot price for crypto assets from various financial information service providers. The closing price and settlement prices of crypto assets are readily available from the crypto asset trading platforms and other publicly available websites.

In addition, such prices are published in public sources, or on-line information services such as Bloomberg and Reuters. The NAV per Share will be calculated daily and made available to all market participants at the same time. The Fund will provide website disclosure of its NAV and NAV per Share daily. In addition, the Fund will make its Crypto Asset Holdings publicly available on its website before the commencement of trading in the Shares on each Business Day. One or more major market data vendors will disseminate for the Fund on a daily basis information with respect to the most recent NAV per Share and Shares outstanding. In addition, if the Exchange becomes aware that the NAV per Share is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV per Share is available to all market participants. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The ITV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session (normally 9:30 a.m. E.T. to 4:00 p.m. E.T.) by one or more major market data vendors. The Exchange represents that the Exchange may halt trading during a day in which it becomes aware of an interruption to the dissemination of the ITV. If the interruption to the dissemination of the ITV persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares on the Exchange and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a CSSA. In addition, as

noted above, investors will have ready access to information regarding the Fund's NAV per Share, ITV, and quotation and last sale information for the Shares.

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. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2025-77 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-2025-77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-NYSEARCA-2025-77 and should be submitted on or before December 19, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁰

Stephanie J. Fouse,
Assistant Secretary.

[FR Doc. 2025-21402 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104252; File No. SR-NASDAQ-2025-037]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To Adopt New Rule 5703 To Permit the Generic Listing and Trading of Class Exchange-Traded Fund Shares

November 24, 2025.

On May 6, 2025, The Nasdaq Stock Market LLC ("Nasdaq" 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 to adopt new Nasdaq Rule 5703 to permit the generic listing and trading of Class Exchange-Traded Fund Shares. The proposed rule change was published for comment in the **Federal Register** on May 27, 2025.³

³⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 103072 (May 20, 2025), 90 FR 22373.

On June 30, 2025, pursuant to 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 August 15, 2025, the Exchange filed Amendment No. 1 to the proposed rule change, and on August 21, 2025, the Commission issued notice of filing of Amendment No. 1 to the proposed rule change and instituted proceedings pursuant to Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.⁷ On November 3, 2025, pursuant to Section 19(b)(2) of the Act,⁸ the Commission designated a longer period for Commission action on the proposed rule change, as modified by Amendment No. 1.⁹ On November 19, 2025, the Exchange filed Amendment No. 2, which amended and replaced the proposed rule change, as modified by Amendment No. 1, in its entirety.¹⁰ The Commission has received no comments regarding the proposed rule change.

The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 2, from interested persons and to grant approval of the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

I. The Exchange's Description of the Proposal, as Modified by Amendment No. 2

The Exchange proposes to adopt Rule 5703 to permit the generic listing and trading of Class Exchange-Traded Fund ("ETF") Shares. The Exchange is also proposing to make conforming changes to Rule 5615 (Exemptions from Certain Corporate Governance Requirements), Rule 5705(b) (Index Fund Shares), Rule 5735 (Managed Fund Shares), and Equity 4, Rule 4120 in order to accommodate the proposed listing of

Class ETF Shares. This Amendment No. 2 to SR-NASDAQ-2025-037 amends and replaces in its entirety Amendment No. 1 as submitted on August 15, 2025. The Exchange submits this Amendment No. 2 in order to clarify certain points and make technical revisions to the proposed rule text.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings> and 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 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 adopt new Rule 5703 for the purpose of permitting the generic listing and trading, or trading pursuant to unlisted trading privileges, of Class ETF Shares.¹¹ The Exchange is also proposing to make conforming changes to Rule 5615 (Exemptions from Certain Corporate Governance Requirements), Rule 5705(b) (Index Fund Shares), Rule 5735 (Managed Fund Shares), and Equity 4, Rule 4120 in order to accommodate the proposed listing of Class ETF Shares. Consistent with Exchange Traded Fund Shares listed under the generic listing standards in Rule 5704, Class ETF Shares would be permitted to be listed and traded on the Exchange without prior Commission approval order or notice of effectiveness pursuant to Section 19(b) of the Act.¹²

¹¹ The Exchange notes that Cboe BZX Exchange, Inc. ("BZX") has filed a substantially similar filing. See Securities Exchange Act Release No. 103188 (June 4, 2025), 90 FR 24457 (June 10, 2025) (SR-CboeBZX-2025-076).

¹² Rule 19b-4(e)(1) provides that the listing and trading of a new derivative securities product by a self-regulatory organization ("SRO") is not deemed a proposed rule change, pursuant to paragraph (c)(1) of Rule 19b-4, if the Commission has approved, pursuant to Section 19(b) of the Act, the SRO's trading rules, procedures and listing standards for the product class that would include

Background

There are numerous applications for exemptive relief for Class ETF Shares currently before the Commission¹³ that request exemptive relief similar to that previously granted to other funds.¹⁴ This proposal would provide for the "generic" listing and/or trading of Class ETF Shares under proposed Rule 5703 on the Exchange.

Starting in 2000, the Commission began granting limited relief for The Vanguard Group, Inc. ("Vanguard") to offer certain index-based open-end management investment companies with Class ETF Shares.¹⁵ After this relief was granted, there was limited public discourse about Class ETF Shares until 2019, when the prospect of providing blanket exemptive relief to Class ETF Shares was addressed in the Commission's adoption of Rule 6c-11 under the Investment Company Act (the

new derivative securities product and the SRO has a surveillance program for the product class. As contemplated by this Rule 5703, the Exchange proposes new Rule 5703 to establish generic listing standards for Class ETF Shares of the ETF Class (as defined herein) that would be required to operate as an ETF pursuant to the Multi-Class Fund Exemptive Relief (as defined herein) and be in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act of 1940 (the "Investment Company Act"), except as noted in the Multi-Class Fund Exemptive Relief. Class ETF Shares listed under proposed Rule 5703 would therefore not need a separate proposed rule change pursuant to Rule 19b-4 before it can be listed and traded on the Exchange.

¹³ See e.g., DFA Investment Dimensions Group Inc. and Dimensional Investment Group Inc., (amendment filed March 31, 2025); F/m Investments LLC (amendment filed April 10, 2025); Fidelity Hastings Street Trust and Fidelity Management & Research Company (amendment filed April 11, 2025); Morgan Stanley Institutional Fund Trust and Morgan Stanley Investment Management Inc. (amendment filed April 11, 2025); BlackRock Funds (amendment filed April 15, 2025); Guinness Atkinson Funds (amendment filed April 17, 2025); Metropolitan West Funds, TCW ETF Trust, and TCW Funds, Inc. (amendment filed April 22, 2025); and Northern Funds and Northern Trust Investments, Inc. (amendment filed May 2, 2025).

¹⁴ See *infra* note 15.

¹⁵ See Vanguard Index Funds, Investment Company Act Release Nos. 24680 (Oct. 6, 2000) (notice) and 24789 (Dec. 12, 2000) (order). The Commission itself, as opposed to the Commission staff acting under delegated authority, considered the original Vanguard application and determined that the relief was appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Investment Company Act. In the process of granting the order, the Commission also considered and denied a hearing request on the original application, as reflected in the final Commission order. See also the Vanguard Group, Inc., Investment Company Act Release Nos. 26282 (Dec. 2, 2003) (notice) and 26317 (Dec. 30, 2003) (order); Vanguard International Equity Index Funds, Investment Company Act Release Nos. 26246 (Nov. 3, 2003) (notice) and 26281 (Dec. 1, 2003) (order); Vanguard Bond Index Funds, Investment Company Act Release Nos. 27750 (Mar. 9, 2007) (notice) and 27773 (April 2, 2007) (order) (collectively referred to as the "Vanguard Orders").

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 103357, 90 FR 29598 (July 3, 2025).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 103758, 90 FR 41611 (Aug. 26, 2025).

⁸ 15 U.S.C. 78s(b)(2).

⁹ See Securities Exchange Act Release No. 104173, 90 FR 51424 (Nov. 17, 2025). The Commission, pursuant to Section 19(b)(2) of the Act, designated January 22, 2026, as the date by which the Commission shall either approve or disapprove the proposed rule change.

¹⁰ Amendment No. 2 to the proposed rule change is available on the Commission's website at: <https://www.sec.gov/comments/sr-nasdaq-2025-037/srnasdaq2025037-677367-2073094.pdf>.

“ETF Rule”).¹⁶ The ETF Rule permits ETFs that satisfy certain conditions to operate without the expense or delay of obtaining an exemptive order. However, the ETF Rule did not provide blanket exemptive relief to allow for Class ETF Shares as part of the final rule. Instead, the Commission concluded that Class ETF Shares should request relief through the exemptive application process so that the Commission may assess all relevant policy considerations in the context of the facts and circumstances of particular applicants. The Exchange adopted Rule 5704 shortly after the implementation of the ETF Rule and, because there were no exemptive applications before the Commission, did not propose to include any language comparable to what is being proposed herein.¹⁷

As noted above, a number of applications for exemptive relief to permit the applicable fund to offer Class ETF Shares (the “Applications”) have been submitted to the Commission starting in early 2023. In general, the Applications state that the ability of a fund to offer Class ETF Shares, *i.e.*, a fund offering both a class of mutual fund shares and a class of shares that are exchange traded, could be beneficial to the fund and to shareholders of each type of class for various reasons, including more efficient portfolio management, better secondary market trading opportunities, and cost efficiencies, among others.¹⁸ The Commission has granted, by order, specific exemptive relief (“Multi-Class Fund Exemptive Relief”) under the Investment Company Act on November 17, 2025, that permits, subject to certain conditions and requirements, a Multi-Class Fund (as defined below) to issue Class ETF Shares (as defined below) and one or more classes of shares that are not exchange traded, among other things.¹⁹

Proposal

Proposed Rule 5703(a) provides that the Exchange will consider for trading, whether by listing or pursuant to unlisted trading privileges, Class ETF

Shares that meet the criteria of this Rule.²⁰

Proposed Rule 5703(b) provides that the proposed rule would be applicable only to Class ETF Shares. Except to the extent inconsistent with this Rule, or unless the context otherwise requires, the rules and procedures of the Board of Directors shall be applicable to the trading on the Exchange of such securities. Class ETF Shares are included within the definition of “security” or “securities” as such terms are used in the Rules of the Exchange.

Proposed Rule 5703(b) further provides that: (1) transactions in Class ETF Shares will occur throughout the Exchange’s trading hours; and (2) the Exchange will implement and maintain written surveillance procedures for Class ETF Shares.

Proposed Rule 5703(c) will set forth the definitions used in the Rule. Specifically, proposed Rule 5703(c)(1) provides that the term “Class ETF Shares” means shares of the ETF Class issued by a Multi-Class Fund.

Proposed Rule 5703(c)(2) provides that the term “ETF Class” means the class of exchange-traded shares of a Multi-Class Fund that (i) operates as an exchange-traded fund pursuant to exemptive relief granted by order under the Investment Company Act (“Multi-Class Fund Exemptive Relief”), and (ii) is in compliance with the requirements of Rules 5703(d)(ii) and 5703(d)(2)(A)(i)(2) below on an initial and continued listing basis.

Proposed Rule 5703(c)(3) provides that the term “Multi-Class Fund” means a registered open-end management company that (i) pursuant to Multi-Class Fund Exemptive Relief, issues Class ETF Shares and one or more classes of shares that are not exchange traded, and (ii) is in compliance with the conditions

and requirements of the Multi-Class Fund Exemptive Relief.

Proposed Rule 5703(c)(4) provides that the term “Reporting Authority” in respect of a particular Multi-Class Fund means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists Class ETF Shares (if the Exchange is trading such securities pursuant to unlisted trading privileges) as the official source for calculating and reporting information relating to such Multi-Class Fund, including, but not limited to, the amount of any dividend equivalent payment or cash distribution to holders of Class ETF Shares, net asset value, index or portfolio value, the current value of the portfolio of securities required to be deposited in connection with the issuance of Class ETF Shares, or other information relating to the issuance, redemption or trading of Class ETF Shares. A Multi-Class Fund may have more than one Reporting Authority, each having different functions.

Proposed Rule 5703(d) provides that the Exchange may approve Class ETF Shares of a Multi-Class Fund for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b-4(e) under the Act, provided that: (i) the Multi-Class Fund is eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (ii) the ETF Class is in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of this Rule 5703, as applicable, on an initial and continued listing basis.

Proposed Rule 5703(d)(1) provides that the requirements of paragraph (d) of this Rule must be satisfied by the Multi-Class Fund issuing the Class ETF Shares on an initial and continued listing basis. The Multi-Class Fund with respect to such Class ETF Shares must also satisfy the following criteria on an initial and, except for sub-paragraph (A) below, continued, listing basis. Further, proposed Rule 5703(d)(1) provides that: (A) for each Multi-Class Fund, the Exchange will establish a minimum number of Class ETF Shares required to be outstanding at the time of commencement of trading on the Exchange; (B) if an index underlying a Multi-Class Fund is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect

¹⁶ See Securities Exchange Act Release No. 33–10695 (September 25, 2019), 84 FR 57162 (October 24, 2019) (the “ETF Rule Adopting Release”).

¹⁷ See Securities Exchange Act Release No. 88561 (April 3, 2020), 85 FR 19984 (April 9, 2020) (SR–NASDAQ–2019–090).

¹⁸ See *supra* note 13.

¹⁹ See Investment Company Act Release No. 35786 (Nov. 17, 2025) (In the Matter of DFA Investment Dimensions Group Inc., Dimensional Investment Group Inc., Dimensional ETF Trust and Dimensional Fund Advisors LP) (File No. 812–15484).

²⁰ To the extent that Class ETF Shares do not satisfy one or more of the criteria in proposed Rule 5703, the Exchange may file a separate proposal under Section 19(b) of the Act in order to list such securities on the Exchange. Any of the statements or representations in that proposal regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index, reference asset, and intraday indicative values (as applicable), or the applicability of Exchange listing rules specified in any filing to list such Class ETF Shares shall constitute continued listing requirements for the Class ETF Shares. Further, in the event that Class ETF Shares become listed under proposed Rule 5703 and subsequently can no longer satisfy the requirements of proposed Rule 5703, such Class ETF Shares may be listed as a series of Index Fund Shares under Rule 5705(b) or Managed Fund Shares under Rule 5735, as applicable, as long as the Class ETF Shares meets all listing requirements applicable under the alternate listing rule. If the Class ETF Shares do change listing standards, the Exchange would have to comply with all of the requirements of Rule 19b-4(e) with respect to such Class ETF Shares.

and maintain a “fire wall” around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to an actively managed Multi-Class Fund is affiliated with a broker-dealer, such investment adviser shall erect and maintain a “fire wall” between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Multi-Class Fund’s portfolio; and (C) any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a Multi-Class Fund, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. For actively managed Multi-Class Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable portfolio.

Proposed Rule 5703(d)(2) provides that Class ETF Shares of each Multi-Class Fund will be listed and traded on the Exchange subject to application of the continued listing criteria therein. Proposed Rule 5703(d)(2)(A) provides that the Exchange will consider the suspension of trading in, and will initiate delisting proceedings under the Rule 5800 Series of, Class ETF Shares under any of the following circumstances: (i) if the Exchange becomes aware, with respect to the Class ETF Shares: (1) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (2) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (ii) if any of the other listing requirements set forth in this Rule are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of the Class ETF Shares, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition

exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 5703(d)(2)(B) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing.

Proposed Rule 5703(e) provides that neither the Exchange, the Reporting Authority, nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the Multi-Class Fund in connection with the issuance of Class ETF Shares; the amount of any dividend equivalent payment or cash distribution to holders of Class ETF Shares; net asset value; or other information relating to the purchase, redemption, or trading of Class ETF Shares, resulting from any negligent act or omission by the Exchange, the Reporting Authority, or any agent of the Exchange, or any act, condition, or cause beyond the reasonable control of the Exchange, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

The Exchange is also proposing to make corresponding amendments to include Class ETF Shares in other Exchange rules, which are intended to align the treatment of the proposed products with how other open-end management investment company shares (e.g., Exchange Traded Fund Shares, Index Fund Shares, and Managed Fund Shares) are treated under the Exchange’s rules. First, the Exchange proposes to amend the definition of “Derivative Securities” in Rule 5615(a)(6)(B) to add Class ETF Shares so that Rule 5615(a)(6)(A) and its exemptions from certain corporate governance requirements are applicable to Class ETF Shares.²¹

²¹ Rule 5615(a)(6)(A) provides that issuers whose only securities listed on Nasdaq are non-voting preferred securities, debt securities or Derivative Securities, are exempt from the requirements relating to Independent Directors (as set forth in Rule 5605(b)), Compensation Committees (as set forth in Rule 5605(d)), Director Nominations (as set forth in Rule 5605(e)), Codes of Conduct (as set

Second, the Exchange proposes to amend the definition of “Derivative Securities Products” in Rule 5705(b)(3)(A)(i)a. to add Class ETF Shares so the exclusions applicable to Derivative Securities Products in Nasdaq Rule 5705(b)(3)(A) will also apply to Class ETF Shares. The Exchange believes this is appropriate to ensure that Class ETF Shares are treated consistently with other open-end management investment company shares listed on the Exchange such as Exchange Traded Fund Shares, Index Fund Shares, and Managed Fund Shares.

Third, the Exchange proposes to amend the definition of “Exchange Traded Derivative Securities” in Rule 5735(c)(6) to add Class ETF Shares so the exclusions applicable to Exchange Traded Derivative Securities in Rule 5735(b)(1)(A) will also apply to Class ETF Shares. The Exchange believes this is appropriate to ensure that Class ETF Shares are treated consistently with other open-end management investment company shares listed on the Exchange such as Exchange Traded Fund Shares, Index Fund Shares, and Managed Fund Shares.

Fourth, the Exchange proposes to amend Equity 4, Rule 4120 to include Class ETF Shares in the Exchange’s trading halt provisions in Rule 4120(a)(9) and 4120(b)(4)(A).²² This will ensure the applicability of trading halts to the trading of Class ETF Shares listed on Nasdaq, and those traded on Nasdaq pursuant to unlisted trading privileges.

Discussion

Proposed Rule 5703 is based on Rule 5704 related to the listing and trading of ETF Shares on the Exchange, which are issued under the Investment Company Act and qualify as ETF Shares under Rule 6c–11. Exchange Traded Fund Shares are similar to Class ETF Shares because the ETF Class is required to operate as an ETF pursuant to the Multi-Class Fund Exemptive Relief and be in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act (except as noted in the Multi-Class Fund

forth in Rule 5610), and Meetings of Shareholders (as set forth in Rule 5620(a)). In addition, these issuers are exempt from the requirements relating to Audit Committees (as set forth in Rule 5605(c)), except for the applicable requirements of SEC Rule 10A–3. Notwithstanding, if the issuer also lists its common stock or voting preferred stock, or their equivalent on Nasdaq it will be subject to all the requirements of the Nasdaq 5600 Rule Series.

²² Rule 4120(b)(4)(A) sets out the definition of “Derivative Securities Product,” which is referenced in the Exchange’s halt authority pursuant to Rules 4120(a)(10) and 4120(b).

Exemptive Relief).²³ The proposed Class ETF Shares generic listing rule would apply only to the class of shares that are exchange traded. Because the ETF Class would be required to comply, among other things, with the conditions and requirements of Rule 6c–11 under the Investment Company Act, similar to Exchange Traded Fund Shares under Rule 5704, the Exchange believes that using Rule 5704 as the basis for proposed Rule 5703 is appropriate.

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices because the Exchange will perform ongoing surveillance of Class ETF Shares listed on the Exchange in order to ensure that (i) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is in otherwise in compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of 5703, as applicable, on an initial and continuing basis. The Exchange believes that the manipulation concerns are mitigated by a combination of the Exchange's surveillance procedures, the Exchange's ability to halt trading under the proposed Rule 5703(d)(2)(B), and the Exchange's ability to suspend trading and commence delisting proceedings under proposed Rule 5703(d)(2)(A). The Exchange will halt trading in the Class ETF Shares under the conditions specified in Nasdaq Rules 4120 and 4121, including without limitation the conditions specified in Nasdaq Rule 4120(a)(9) and (10) and under Nasdaq Rules 4120(a)(12). The Exchange also believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that have come from Rule 6c–11, specifically the additional flexibility provided through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c–11.²⁴ The Exchange also notes that there are firewall and other information barrier restrictions in place in the proposed

rule text.²⁵ The Exchange believes that the combination of these factors will act to keep Class ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of Class ETF Shares on the Exchange. The Exchange will monitor for compliance to ensure that (i) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is in otherwise in compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of 5703, as applicable, on an initial and continuing basis. Specifically, the Exchange will review the website of Class ETF Shares listed on the Exchange in order to ensure that the requirements of Rule 6c–11 are being met. The Exchange will also employ numerous intraday alerts that will notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. As a backstop to the surveillances described above, the Exchange also notes that Rule 5703 would require an issuer of Class ETF Shares to notify the Exchange of any failure to comply with the requirements of proposed Rule 5703, the Multi-Class Fund Exemptive Relief, or Rule 6c–11 under the Investment Company Act.

The Exchange may suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable.²⁶ The Exchange also notes

that Rule 5701(d) requires any issuer to provide the Exchange with prompt notification after it becomes aware that (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or otherwise no longer complies with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class is no longer compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, or (iii) the ETF Class or the Multi-Class Fund no longer satisfies the requirements of 5703, as applicable, on an initial and continuing basis.²⁷

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the Class ETF Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Exchange Traded Fund Shares, Index Fund Shares and Managed Fund Shares, among other product types, to monitor trading in Class ETF Shares. The Exchange or the Financial Industry Regulatory Authority, Inc. ("FINRA"), on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the Intermarket Surveillance Group ("ISG") or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying

the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (ii) if any of the other listing requirements set forth in this Rule are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of Class ETF Shares, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 5703(d)(2)(B) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing.

²⁷ The Exchange notes that failure by an issuer to notify the Exchange of non-compliance pursuant to Rule 5701(d) would itself be considered non-compliance with the requirements of proposed Rule 5703 and would subject the Class ETF Shares to potential trading halts and the delisting process under the Rule 5800 Series.

²³ See *supra* note 19.

²⁴ The Exchange notes that the Commission came to a similar conclusion in several places in the ETF Rule Adopting Release. See ETF Rule Adopting Release at 15–18; 60–61; 69–70; 78–79; 82–84; and 95–96.

²⁵ See proposed Rules 5703(d)(1)(B) and (C).

²⁶ Specifically, proposed Rule 5703(d)(2) provides that Class ETF Shares will be listed and traded on the Exchange subject to application of Proposed Rule 5703(d)(2)(A) and (B). Proposed Rule 5703(d)(2)(A) provides that the Exchange will consider the suspension of trading in, and will commence delisting proceedings under the Rule 5800 Series of, Class ETF Shares under any of the following circumstances: (i) if the Exchange becomes aware, with respect to the Class ETF Shares: (1) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (2) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c–11 under

components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Finally, the issuer of Class ETF Shares will be required to comply with Rule 10A-3 under the Act for the initial and continued listing of Class ETF Shares, as provided under Rule 5615(a)(6).²⁸

The Exchange notes that it may consider all relevant factors in exercising its discretion to halt or suspend trading in Class ETF Shares. Trading may be halted if the circuit breaker parameters in Rule 4121 have been reached, because of other market conditions, or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) the extent to which certain information about the Class ETF Shares that is required to be disclosed under Rule 6c-11 of the Investment Company Act is not being made available, including specifically where the Exchange becomes aware that the net asset value or the daily portfolio disclosure with respect to Class ETF Shares is not disseminated to all market participants at the same time, it will halt trading in such securities until such time as the net asset value or the daily portfolio disclosure is available to all market participants;²⁹ (2) if an interruption to the dissemination to the value of the index or reference asset on which Class ETF Shares is based persists past the trading day in which it occurred or is no longer calculated or available; (3) trading in the securities comprising the underlying index or portfolio has been halted in the primary market(s); or (4) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. The Exchange deems Class ETF Shares to be equity securities and therefore they would be subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.³⁰

²⁸ See *supra* note 21. The Exchange notes that these proposed changes in Rule 5615(a)(6)(B) would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange.

²⁹ The Exchange will obtain a representation from the issuer of Class ETF Shares that the net asset value per share will be calculated daily and made available to all market participants at the same time, and the requirements pertaining to the Multi-Class Fund Exemptive Relief and Rule 6c-11 under the Investment Company Act in proposed Rule 5703 will be satisfied.

³⁰ With respect to trading in Class ETF Shares, the Exchange represents that all of the Nasdaq member obligations relating to product description and prospectus delivery requirements will continue to

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,³¹ in general, and furthers the objectives of Section 6(b)(5) of the Act,³² in particular, in that 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.

The Exchange believes that proposed Rule 5703 is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading Class ETF Shares on the Exchange provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 5703(d) sets forth initial and continued listing criteria applicable to Class ETF Shares, specifically providing that the Exchange may approve Class ETF Shares for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b-4(e) under the Act, provided that: (i) the Multi-Class Fund is eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (ii) the ETF Class is in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of this Rule 5703, as applicable, on an initial and continued listing basis.³³ The Exchange will

apply in accordance with the Exchange's rules and federal securities laws, and Nasdaq will continue to monitor its members for compliance with such requirements, which are not changing as a result of the Multi-Class Fund Exemptive Relief order issued under the Investment Company Act.

³¹ 15 U.S.C. 78f(b).

³² 15 U.S.C. 78f(b)(5).

³³ The Exchange notes that eligibility to operate in reliance on Rule 6c-11 or any applicable exemptive relief under the Investment Company Act does not necessarily mean that an investment company would be listed on the Exchange pursuant to proposed Rule 5703. To this point, an investment company that operates in reliance of exemptive relief providing for Class ETF Shares could alternatively be listed as a series of Index Fund Shares or Managed Fund Shares pursuant to Rule 5705(b) or 5735, respectively, and would be subject to all requirements under each of those rules. Further to this point, in the event that Class ETF Shares listed on the Exchange preferred to be listed as a series of Index Fund Shares or Managed Fund Shares (as applicable), nothing would preclude such security from changing to be listed as a series of Index Fund Shares or Managed Fund Shares (as applicable), as long as the security met each of the initial and continued listing obligations under the applicable rules.

comply with all the requirements of Rule 19b-4(e) to specifically note that such Class ETF Shares are being listed on the Exchange pursuant to Rule 5703.

Proposed Rule 5703(d)(2) provides that Class ETF Shares of each Multi-Class Fund will be listed and traded on the Exchange subject to application of proposed Rules 5703(d)(2)(A) and (B). Proposed Rule 5703(d)(2)(A) provides that the Exchange will consider the suspension of trading in, and will initiate delisting proceedings under the Rule 5800 Series of, Class ETF Shares under any of the following circumstances: (i) if the Exchange becomes aware, with respect to the Class ETF Shares: (1) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (2) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (ii) if any of the other listing requirements set forth in this Rule 5703 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of the Class ETF Shares, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. The Exchange notes that it may become aware that the issuer is no longer compliant with Rule 6c-11 or any applicable exemptive relief thereunder, as described in proposed Rule 5703(d)(2)(A)(i), as a result of either the Exchange identifying non-compliance through its own monitoring process or through notification by the issuer.

Proposed Rule 5703(d)(2)(B) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing. The Exchange also notes that it will obtain a representation from the issuer of Class ETF Shares stating that the requirements of Rule 6c-11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied and that the issuer will notify the Exchange of any failure to do so.

The Exchange further believes that proposed Rule 5703 is designed to prevent fraudulent and manipulative

acts and practices because of the robust surveillances in place on the Exchange as required under proposed Rule 5703(b)(2) along with the similarities of proposed Rule 5703 to the rules related to other securities that are already listed and traded on the Exchange and which would qualify as Class ETF Shares. ETF Shares are identical to Class ETF Shares except that Class ETF Shares have received exemptive relief to operate an exchange-traded fund class in addition to classes of shares that are not exchange-traded. As such, the Exchange believes because the ETF Class would be required to comply, among other things, with the conditions and requirements of Rule 6c–11 under the Investment Company Act, similar to an exchange-traded fund under Rule 5704, the Exchange believes that using Rule 5704 as the basis for proposed Rule 5703 is appropriate.

The Exchange believes that the proposal is consistent with Section 6(b)(1) of the Act³⁴ in that, in addition to being designed to prevent fraudulent and manipulative acts and practices, the Exchange has the capacity to enforce proposed Rule 5703 by performing ongoing surveillance of Class ETF Shares listed on the Exchange in order to ensure that (i) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is in otherwise in compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of 5703, as applicable, on an initial and continuing basis. The Exchange believes that the manipulation concerns that such standards are intended to address are mitigated by a combination of the Exchange's surveillance procedures, the Exchange's ability to halt trading under the proposed Rule 5703(d)(2)(B), and the Exchange's ability to suspend trading and commence delisting proceedings under proposed Rule 5703(d)(2)(A). The Exchange also believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that have come from compliance with Rule 6c–11, specifically the additional flexibility provided through the use of custom baskets for creations and redemptions and the additional information made available to the public through the

additional daily website disclosure obligations applicable under Rule 6c–11.³⁵ The Exchange believes that the combination of these factors will act to keep Class ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of Class ETF Shares on the Exchange. The Exchange will monitor for compliance with Rule 6c–11 and any applicable exemptive relief in order to ensure that the continued listing standards are being met. Specifically, the Exchange plans to review the website of Class ETF Shares in order to ensure that the requirements of Rule 6c–11 are being met. The Exchange will also employ numerous intraday alerts that will notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. As a backstop to the surveillances described above, the Exchange also notes that Rule 5701(d) would require an issuer of Class ETF Shares to notify the Exchange of any failure to comply with Rule 6c–11 or the requirements of the Multi-Class Fund Exemptive Relief under the Investment Company Act.

To the extent that any of the requirements under Rule 6c–11 or the Multi-Class Fund Exemptive Relief under the Investment Company Act are not being met, the Exchange may halt trading in Class ETF Shares as provided in proposed Rule 5703(d)(2)(B). Further, the Exchange may also suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable. As discussed above, the Exchange also notes that Rule 5701(d) requires any issuer to provide the Exchange with prompt notification after it becomes aware of any non-compliance with proposed Rule 5703, which would include any failure of the issuer to comply with Rule 6c–11 or the Multi-Class Fund Exemptive Relief under the Investment Company Act.

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the Class ETF Shares in all trading sessions and to deter and detect

violations of Exchange rules. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Index Fund Shares, Managed Fund Shares and ETF Shares, among other product types, to monitor trading in Class ETF Shares. The Exchange or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a Multi-Class Fund for the Class ETF Shares reported to FINRA's TRACE. FINRA also can access data obtained from the MSRB's EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in Class ETF Shares, to the extent that the Multi-Class Fund for the Class ETF Shares holds municipal securities. Finally, as noted above, the issuer of Class ETF Shares will be required to comply with Rule 10A–3 under the Act for the initial and continued listing of Class ETF Shares, as provided under Rule 5615(a)(6).³⁶

The Exchange believes that permitting Class ETF Shares to list on the Exchange will help perfect the mechanism of a free and open market and, in general, will protect investors and the public interest in that it will permit the listing and trading of Class ETF Shares, consistent with the applicable exemptive relief, and in a manner that will benefit investors. Specifically, the Exchange believes that the relief proposed in the Applications and the expected benefits of the Class ETF Shares described above would be to the benefit of investors.

The Exchange also believes that proposed Rule 5703 to explicitly provide the initial and continued listing standards applicable to Class ETF Shares, including the suspension of trading or removal standards, are

³⁵ The Exchange notes that the Commission came to a similar conclusion in several places in the ETF Rule Adopting Release. See ETF Rule Adopting Release at 15–18; 60–61; 69–70; 78–79; 82–84; and 95–96.

³⁴ 15 U.S.C. 78f(b)(1).

³⁶ See *supra* notes 21 and 28.

designed to promote transparency and clarity in the Exchange's Rules.

The Exchange also believes that the corresponding changes to add Class ETF Shares in the Exchange's corporate governance requirements under Rule 5615(a)(6)(B), the Index Fund Shares provisions in Rule 5705(b), the Managed Fund Shares provisions in Rule 5735, and the trading halt provisions in Equity 4, Rule 4120, each as discussed in detail above, will add clarity to the Exchange's Rulebook. ETF Shares, Managed Fund Shares, and Index Fund Shares are similarly included in these provisions. Therefore, the Exchange believes these are non-substantive changes meant only to subject Class ETF Shares to the same exemptions and provisions currently applicable to ETF Shares, among other product types, so that the treatment of these open-end management investment companies is consistent under the Exchange's rules.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposal, by permitting the listing and trading of Class ETF Shares under exemptive relief from the Investment Company Act and the rules and regulations thereunder, would introduce additional competition among various ETF products to the benefit of investors.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.³⁷ In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with

Section 6(b)(5) of the Act,³⁸ which requires, among other things, that the Exchange's rules 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, in general, to protect investors and the public interest. The Commission also finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 11A(a)(1)(C)(iii) of the Act, which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.³⁹ In addition, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(1) of the Act,⁴⁰ which requires, among other things, that the Exchange is so organized and has the capacity to be able to enforce compliance by its members and persons associated with its members with the rules of the Exchange.

The Exchange proposes to adopt new Nasdaq Rule 5703 to permit the generic listing and trading, or trading pursuant to unlisted trading privileges, of Class ETF Shares in connection with the Multi-Class Fund Exemptive Relief granted by order under the Investment Company Act.⁴¹ Under the proposal and pursuant to the Multi-Class Fund Exemptive Relief, a Multi-Class Fund is permitted to issue a class of shares that are exchange-traded (*i.e.*, ETF Class) and one or more classes of shares that are not exchange-traded. In accordance with the Multi-Class Fund Exemptive Relief, the ETF Class operates as an ETF in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in the Multi-Class Fund Exemptive Relief. The Exchange also proposes to make conforming changes to Nasdaq Rule 5615 (Exemptions from Certain Corporate Governance Requirements), Nasdaq Rule 5705(b) (Index Fund Shares), Nasdaq Rule 5735 (Managed Fund Shares), and Equity 4, Nasdaq Rule 4120 in order to accommodate the proposed listing of Class ETF Shares.

A. Consistency With Section 6(b)(5) of the Act

(1) Proposed Nasdaq Rule 5703

Proposed Nasdaq Rule 5703 is reasonably designed to help prevent fraudulent and manipulative acts and practices. Proposed Nasdaq Rule 5703 is based on Nasdaq Rule 5704, which governs the generic listing and trading of ETF Shares on the Exchange.⁴² Under current Nasdaq Rule 5704, ETF Shares, which must be eligible to operate in reliance on Rule 6c–11 under the Investment Company Act and must satisfy the requirements of Rule 6c–11 under the Investment Company Act on an initial and continued listing basis, are similar to Class ETF Shares because, under the proposal, the ETF Class also is required to operate as an ETF and be in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act (except as noted in the Multi-Class Fund Exemptive Relief).⁴³

As stated in the ETF Shares Approval Order, a central qualification for listing under the proposed rule is ongoing compliance with Rule 6c–11 under the Investment Company Act, which requires, among other things, ETFs to prominently disclose the portfolio holdings that will form the basis for each calculation of net asset value per share.⁴⁴ Because initial and ongoing compliance with Rule 6c–11 of the Investment Company Act is a condition for listing and trading Class ETF Shares on the Exchange,⁴⁵ proposed Nasdaq Rule 5703 would permit the Exchange to list and trade shares of an investment company with a fully transparent

⁴² See Nasdaq Rule 5704. See also *supra* note 17 and accompanying text; Securities Exchange Act Release No. 88561 (April 3, 2020), 85 FR 19984 (Apr. 9, 2020) (SR-NASDAQ-2019-090) ("ETF Shares Approval Order").

⁴³ The Exchange represents that the proposed Class ETF Shares generic listing rules apply only to the class of shares (ETF Class) that are exchange-traded.

⁴⁴ See ETF Shares Approval Order, *supra* note 42, 85 FR at 19992. See also ETF Rule Adopting Release, *supra* note 16, 84 FR at 57180–81.

⁴⁵ See proposed Nasdaq Rule 5703(d) ("The Exchange may approve Class ETF Shares of a Multi-Class Fund for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b–4(e) under the Act, provided that . . . the ETF Class is in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act of 1940, except as noted in such Multi-Class Fund Exemptive Relief") and Nasdaq Rule 5703(d)(2)(A) ("The Exchange will consider the suspension of trading in, and will initiate delisting proceedings under the Rule 5800 Series of, Class ETF Shares . . . if the Exchange becomes aware that, with respect to the Class ETF Shares . . . the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act of 1940, except as noted in such Multi-Class Fund Exemptive Relief").

³⁷ In approving this proposed rule change, as modified by Amendment No. 2, 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(b)(5).

³⁹ See 15 U.S.C. 78k–1(a)(1)(C)(iii).

⁴⁰ 15 U.S.C. 78f(b)(1).

⁴¹ See *supra* note 19 and accompanying text.

portfolio,⁴⁶ and as the Commission previously stated for ETF Shares,⁴⁷ portfolio transparency should equally help prevent manipulation of the price of Class ETF Shares.⁴⁸ Additionally, proposed Nasdaq Rule 5703 includes requirements relating to fire walls and procedures to prevent the use and dissemination of material, non-public information regarding the applicable Multi-Class Fund index and portfolio,⁴⁹ all such requirements of which are substantively identical to those applicable to ETF Shares under Nasdaq Rule 5704 and are designed to prevent fraudulent and manipulative acts and practices.⁵⁰ Certain of these

⁴⁶ The Commission stated that, with respect to ETF portfolio transparency, the disclosures are designed to promote an effective arbitrage mechanism and inform investors about the risks of deviation between market price and net asset value when deciding whether to invest in ETFs generally or in a particular ETF. See ETF Rule Adopting Release, *supra* note 16, 84 FR at 57166.

⁴⁷ See ETF Shares Approval Order, *supra* note 42, 85 FR at 19992 (concluding that because initial and ongoing compliance with Rule 6c–11 of the Investment Company Act is a condition for listing and trading on the Exchange, the proposed rule would permit the listing and trading of shares of an investment company with a fully transparent portfolio, and the Commission believes that portfolio transparency should help prevent manipulation of the price of ETF Shares).

⁴⁸ See ETF Rule Adopting Release, *supra* note 16, 84 FR at 57169 (concluding that portfolio transparency combined with existing requirements should be sufficient to protect against certain abuses).

⁴⁹ For example, proposed Nasdaq Rule 5703(d)(1)(B) provides that if an index underlying a Multi-Class Fund is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a “fire wall” around the personnel who have access to information concerning changes and adjustments to the index, and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. Proposed Nasdaq Rule 5703(d)(1)(B) further states that if the investment adviser to an actively managed Multi-Class Fund is affiliated with a broker-dealer, such investment adviser shall erect and maintain a “fire wall” between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Multi-Class Fund’s portfolio. Proposed Nasdaq Rule 5703(d)(1)(C) requires that any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a Multi-Class Fund, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable index. For actively managed Multi-Class Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable portfolio. See generally proposed Nasdaq Rule 5703(d)(1)(C). Compare proposed Nasdaq Rule 5703(d) (encompassing the initial and continued listing requirements for Class ETF Shares) with Nasdaq Rule 5704(b) (encompassing the initial and continued listing requirements for ETF Shares).

⁵⁰ In adopting Rule 6c–11 under the Investment Company Act, the Commission stated that the safeguards in the existing regulatory regime

requirements relating to such fire walls and procedures apply in addition to what is already required under the Act and the Investment Company Act and respective rules and regulations thereunder, and such requirements collectively provide additional protections against the potential misuse of material, non-public information.⁵¹ The Commission concludes that the proposed requirements relating to such fire walls and procedures, combined with Multi-Class Fund portfolio transparency with respect to the ETF Class and the existing requirements under the Act and Investment Company Act, should help to protect against fraudulent and manipulative acts and practices under Section 6(b)(5) of the Act.⁵²

Proposed Nasdaq Rule 5703(b)(2) requires that the Exchange implement and maintain written surveillance procedures for Class ETF Shares. The Exchange represents that it will utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to ETF Shares, among other product types, to monitor trading in Class ETF Shares, and further represents that its surveillance procedures are adequate to (a) properly monitor the trading of the Class ETF Shares during all trading sessions and (b) deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange also represents that the Exchange, or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain

adequately address “special concerns that self-indexed ETFs present, including the potential ability of an affiliated index provider to manipulate an underlying index to the benefit or detriment of a self-indexed ETF.” See ETF Rule Adopting Release, *supra* note 16, 84 FR at 57168. See also ETF Shares Approval Order, *supra* note 42, 85 FR at 19992 (concluding that the requirements of Nasdaq Rule 5704, which includes provisions relating to fire walls and procedures to prevent the use and dissemination of material, non-public information regarding the applicable ETF index and portfolio for ETF Shares, are designed to prevent fraudulent and manipulative acts and practices).

⁵¹ See ETF Shares Approval Order, *supra* note 42, 85 FR at 19992 (stating that the requirements for ETF Shares relating to fire walls and procedures, which are substantively identical to Nasdaq’s rules governing the listing and trading of index-based and actively managed ETFs, apply in addition to what is already required under the Act and the Investment Company Act and respective rules and regulations thereunder, and that such requirements collectively provide additional protections against the potential misuse of material, non-public information).

⁵² See *id.* (“Therefore, the Commission concludes that the proposed requirements relating to such fire walls and procedures, combined with ETF portfolio transparency and the existing requirements under the Act and [Investment Company Act], should help to protect against fraudulent and manipulative acts and practices under Section 6(b)(5) of the Act.”).

of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange also may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a Multi-Class Fund for the Class ETF Shares reported to TRACE. FINRA also can access data obtained from the EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in Class ETF Shares, to the extent that the Multi-Class Fund for the Class ETF Shares holds municipal securities. The Exchange states that Nasdaq Rule 5701(d) requires any issuer to provide the Exchange with prompt notification after it becomes aware that (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or otherwise no longer complies with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class is no longer compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, or (iii) the ETF Class or the Multi-Class Fund no longer satisfies the requirements of Nasdaq Rule 5703, as applicable, on an initial and continuing basis.⁵³ The Exchange further states that it will obtain a representation from the issuer of Class ETF Shares stating that the requirements of Rule 6c–11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied and that the issuer will notify the Exchange of any failure to do so.

Consistent with the requirement of Section 6(b)(5) of the Act⁵⁴ that the Exchange’s rules be designed to remove impediments to and perfect the mechanism of a free and open market, the Exchange’s rules regarding trading halts will help to ensure the maintenance of fair and orderly markets

⁵³ See *supra* note 27 and accompanying text. See also Nasdaq Rule 5701(d) (requiring that “[a] Company with securities listed under this Rule 5700 Series must provide Nasdaq with prompt notification after the Company becomes aware of any noncompliance by the Company with the requirements of the Rule 5700 Series.”).

⁵⁴ 15 U.S.C. 78f(b)(5).

for Class ETF Shares. Specifically, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in Class ETF Shares. The Exchange states that trading in Class ETF Shares may be halted if the circuit breaker parameters in Nasdaq Rule 4121 have been reached, because of other market conditions, or for reasons that, in the view of the Exchange, make trading in the Class ETF Shares inadvisable. According to the Exchange, the reasons to halt trading may include: (1) the extent to which certain information about the Class ETF Shares that is required to be disclosed pursuant to Rule 6c–11 under the Investment Company Act is not being made available;⁵⁵ (2) if an interruption to the dissemination to the value of the index or reference asset on which the Class ETF Shares is based persists past the trading day in which it occurred or is no longer calculated or available; (3) trading in the securities comprising the underlying index or portfolio has been halted in the primary market(s); or (4) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. As the Exchange further represents in the proposal, if the Exchange becomes aware that the net asset value or the daily portfolio disclosure with respect to the Class ETF Shares is not disseminated to all market participants at the same time, it will halt trading in the Class ETF Shares until such time as the net asset value or the daily portfolio disclosure is available to all market participants.⁵⁶ The Exchange represents that it may suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable.⁵⁷

The Commission also finds that, consistent with Section 11A(a)(1)(C)(iii) of the Act,⁵⁸ the proposed rule change, as modified by Amendment No. 2, is reasonably designed to promote fair disclosure of information that may be necessary to price the Class ETF Shares appropriately, to prevent trading when a reasonable degree of transparency

cannot be assured, to safeguard material non-public information relating to the Class ETF Shares, and to ensure fair and orderly markets for Class ETF Shares.

(2) Other Related Proposed Rule Changes

The Exchange also proposes changes to accommodate Class ETF Shares in other Exchange rules. The Exchange proposes to amend: (1) the definition of “Derivative Securities” in Nasdaq Rule 5615(a)(6)(B) to add Class ETF Shares so that Nasdaq Rule 5615(a)(6)(A) and its exemptions from certain corporate governance requirements are applicable to Class ETF Shares;⁵⁹ and (2) the definition of “Derivative Securities Products” in Nasdaq Rule 5705(b)(3)(A)(i)a. to add Class ETF Shares so that the exclusions applicable to Derivative Securities Products in Nasdaq Rule 5705(b)(3)(A) will also apply to Class ETF Shares. In addition, the Exchange proposes to amend the definition of “Exchange Traded Derivative Securities” in Nasdaq Rule 5735(c)(6) to add Class ETF Shares so the exclusions applicable to Exchange Traded Derivative Securities in Nasdaq Rule 5735(b)(1)(A) will also apply to Class ETF Shares. The Exchange also proposes to amend Equity 4, Nasdaq Rule 4120 to include Class ETF Shares in the Exchange’s trading halt provisions in Nasdaq Rules 4120(a)(9) and 4120(b)(4)(A)⁶⁰ to ensure the applicability of trading halts to the trading of Class ETF Shares listed on Nasdaq, and those traded on Nasdaq pursuant to unlisted trading privileges.⁶¹ These proposed changes incorporate proposed Nasdaq Rule 5703 into the existing framework of Nasdaq’s rules, and therefore the Commission finds that such changes are consistent with Section 6(b)(5) of the Act.

B. Consistency With Section 6(b)(1) of the Act

The Commission also finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(1) of the Act,⁶² which requires, among other things, that the Exchange is so organized and has the capacity to be able to enforce compliance by its members and persons associated with its members with the rules of the Exchange. The Exchange

represents that, consistent with Section 6(b)(1) of the Act,⁶³ it has the capacity to enforce proposed Nasdaq Rule 5703 and that it will perform ongoing surveillance of Class ETF Shares listed on the Exchange to ensure that: (1) the Multi-Class Fund is and continues to be eligible to operate an ETF Class as an ETF pursuant to, and is otherwise in compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief; (2) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (3) the ETF Class and the Multi-Class Fund each satisfies the requirements of proposed Nasdaq Rule 5703, as applicable, on an initial and continued listing basis. In addition, the Exchange represents that it will review the website of the Class ETF Shares to ensure that the requirements of Rule 6c–11 under the Investment Company Act are being met, and will obtain a representation from the issuer of the Class ETF Shares that the requirements of Rule 6c–11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied, and that the issuer will notify the Exchange of any failure to do so. The Exchange also represents that it will comply with all the requirements of Rule 19b–4(e) to specifically note that such Class ETF Shares are being listed on the Exchange pursuant to Nasdaq Rule 5703.⁶⁴

The Exchange states that it will employ numerous intraday alerts to notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. The Exchange also states that Nasdaq Rule 5701(d) requires any issuer to provide the Exchange with prompt notification after it becomes aware of any non-

⁶³ *Id.*

⁶⁴ Rule 19b–4(e) requires an SRO seeking to rely on Rule 19b–4(e) to post on its publicly available internet website within five business days after commencement of trading a new derivative securities product the following information relating to the new derivative securities product, using the most recent versions of the XML schema and the associated PDF renderer as published on the Commission’s website: (A) type of issuer; (B) class; (C) name of underlying instrument; (D) if the underlying instrument is an index, whether it is broad-based or narrow-based; (E) ticker symbol(s); (F) market(s) upon which securities composing the underlying instrument trade; (G) settlement methodology; and (H) position limits (if applicable). See 17 CFR 240.19b–4(e)(2)(ii). See also *supra* note 20 and accompanying text.

⁵⁵ The Exchange will obtain a representation from the issuer of Class ETF Shares that the net asset value per share will be calculated daily and made available to all market participants at the same time, and the requirements pertaining to the Multi-Class Fund Exemptive Relief and Rule 6c–11 under the Investment Company Act in proposed Nasdaq Rule 5703 will be satisfied. See *supra* note 29 and accompanying text.

⁵⁶ See *id.*

⁵⁷ See *supra* note 26 and accompanying text.

⁵⁸ See *supra* note 39 and accompanying text.

⁵⁹ See *supra* note 21 and accompanying text.

⁶⁰ See *supra* note 22 and accompanying text.

⁶¹ The Exchange states that these proposed changes would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange. See *supra* note 28 and accompanying text.

⁶² 15 U.S.C. 78f(b)(1).

compliance with proposed Nasdaq Rule 5703,⁶⁵ which would include any failure of the issuer to comply with Rule 6c–11 under the Investment Company Act or with the terms and conditions of the Multi-Class Fund Exemptive Relief.⁶⁶ Further, proposed Nasdaq Rule 5703(d)(2)(A)(iii) requires that the Exchange commence delisting proceedings for Class ETF Shares if, following the initial 12-month period after commencement of trading on the Exchange, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days.⁶⁷ Finally, the Exchange deems Class ETF Shares to be equity securities and represents, therefore, that such Class ETF Shares would be subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.⁶⁸ The Exchange states that Class ETF Shares will be subject to rules governing Exchange member disclosure obligations in connection with equities trading, and that Rule 6c–11 under the Investment Company Act does not change the applicability of these Exchange rules with respect to these securities.⁶⁹

This approval order is based on all of the Exchange's representations and descriptions in the proposed rule change, including those set forth above and in Amendment No. 2, which the Commission has carefully evaluated as discussed above. For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Sections 6(b)(1) and 6(b)(5) of the Act⁷⁰ and the rules and regulations

thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendment No. 2 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether the proposed rule change, as modified by Amendment No. 2, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–NASDAQ–2025–037 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to file number SR–NASDAQ–2025–037. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2025–037 and should be submitted on or before December 19, 2025.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 2

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 2, prior to the 30th day after the date of publication of Amendment No. 2 in the **Federal Register**. Amendment No. 2 reflects the Commission's grant of the Multi-Class Fund Exemptive Relief and provides additional clarity with respect to the application of the Exchange's proposed listing standards and the requirements of the Multi-Class Fund Exemptive Relief. Amendment No. 2 also makes certain additional corrections that are minor and technical

in nature. In addition, the proposal, as modified by Amendment No. 1, has been subject to public comment and no comments have been received.

The Commission finds that Amendment No. 2 to the proposed rule change raises no novel regulatory issues that have not previously been subject to comment, and is reasonably designed, among other things, to prevent fraudulent and manipulative acts and practices, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest. The Commission also finds that Amendment No. 2 to the proposed rule change is consistent with Section 11A(a)(1)(C)(iii) of the Act.⁷¹ Accordingly, pursuant to Section 19(b)(2) of the Act,⁷² the Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁷³ that the proposed rule change (SR–NASDAQ–2025–037), as modified by Amendment No. 2, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–21406 Filed 11–26–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0211]

Agency Information Collection Activities; Comment Request; Extension: Rule 18f–1 and Form N–18f–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

⁷¹ See *supra* note 39 and accompanying text.

⁷² 15 U.S.C. 78s(b)(2).

⁷³ *Id.*

⁷⁴ 17 CFR 200.30–3(a)(12).

⁶⁵ See Nasdaq Rule 5701(d) (requiring a company with securities listed under the Nasdaq Rule 5700 Series to provide the Exchange with prompt notification after the company becomes aware of any non-compliance by the company with the requirements of the Nasdaq Rule 5700 Series). See *supra* note 53 and accompanying text.

⁶⁶ The Exchange further represents that failure by an issuer to notify the Exchange of non-compliance pursuant to Nasdaq Rule 5701(d) would itself be considered non-compliance with the requirements of Nasdaq Rule 5703 and would subject the Class ETF Shares to potential trading halts and the delisting process under the Nasdaq Rule 5800 Series. See *supra* note 27 and accompanying text.

⁶⁷ See proposed Nasdaq Rule 5703(d)(2)(A)(iii).

⁶⁸ See *supra* note 30 and accompanying text.

⁶⁹ With respect to trading in Class ETF Shares, the Exchange further represents that all of the Nasdaq member obligations relating to product description and prospectus delivery requirements will continue to apply in accordance with the Exchange rules and federal securities laws, and Nasdaq will continue to monitor its members for compliance with such requirements, which are not changing as a result of the Multi-Class Fund Exemptive Relief order issued under the Investment Company Act. See *supra* note 30 and accompanying text.

⁷⁰ 15 U.S.C. 78f(b)(1) and 15 U.S.C. 78f(b)(5), respectively.

Rule 18f-1 (17 CFR 270.18f-1) enables a registered open-end management investment company (“fund”) that may redeem its securities in-kind, by making a one-time election, to commit to make cash redemptions pursuant to certain requirements without violating section 18(f) of the Investment Company Act of 1940 (15 U.S.C. 80a-18(f)). A fund relying on the rule must file Form N-18F-1 (17 CFR 274.51) to notify the Commission of this election. The Commission staff estimates that 8 funds file Form N-18F-1 annually, and that each response takes one hour. Based on these estimates, the total annual burden hours associated with the rule is estimated to be 8 hours. The estimated burden hours associated with rule 18f-1 and Form 18F-1 have decreased by 4 hours from the current allocation of 12 hours. This decrease is due to a decrease in the estimated number of investment companies filing Form N-18F-1 annually. There is no external cost associated with this collection of information.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. The collection of information required by rule 18f-1 is necessary to obtain the benefits of the rule. Responses to the collection of information will not be kept confidential.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202509-3235-006 or send an email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice by December 29, 2025.

Dated: November 24, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21389 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104250; File No. SR-NSCC-2025-015]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NSCC Rules To Align With Exchange Act Rule 17ad-26

November 24, 2025.

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 November 21, 2025, National Securities Clearing Corporation (“NSCC”) 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 clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(4) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change certain changes to Rule 42 (Wind-down of the Corporation) of the Rules of National Securities Clearing Corporation (“NSCC”)⁵ to revise certain defined terms and make related technical changes to align with Exchange Act Rule 17ad-26⁶ (“SEC Rule 17ad-26” or “Rule 17ad-26”) promulgated by the Commission.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared

summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission promulgated Rule 17ad-26,⁷ which requires that plans for the recovery and orderly wind-down of a covered clearing agency, such as NSCC, include certain specific elements. The Commission recently approved NSCC’s proposed rule change to reflect the requirements of Rule 17ad-26 in the NSCC Recovery & Wind-down Plan (the “Plan” or “RWP”).⁸ For purposes of implementing certain aspects of the RWP, NSCC is proposing to revise certain defined terms and make certain technical changes to NSCC Rule 42 (Wind-down of the Corporation),⁹ in order to align with how they are referred to in the Plan and to conform with the definitions set forth in Rule 17ad-26.¹⁰

A. Proposal To Modify or Add Certain Defined Terms in NSCC Rule 42 (Wind-down of the Corporation)

(i) Proposal To Replace the Term “Critical Services” With “Core Services”

Consistent with SEC Rule 17ad-26(a)(1),¹¹ NSCC is proposing to modify NSCC Rule 42 to replace all references to “Critical Services” with “Core Services.” Use of the descriptive term “Core” rather than “Critical” would not affect NSCC’s identification, classification or description of these services in the RWP. Similarly, the proposed rule filing would replace all

⁷ *Id.*

⁸ See Securities Exchange Act Release No. 103221 (June 10, 2025), 90 FR 25414 (June 16, 2025) (SR-NSCC-2025-007).

⁹ NSCC Rule 42 (Wind-down of the Corporation), *supra*, note 5.

¹⁰ *Supra* note 6.

¹¹ *Id.* In the Adopting Release covering Rule 17ad-26, it was noted that “The Commission is modifying the final rule to refer to “core payment, clearance, and settlement services” rather than “critical payment, clearance, and settlement services” (hereinafter, referred to as “core services”) to improve clarity and consistency with terminology in other rules, such as Rule 17ad-25(i), 242 which concerns the governance of “service providers for core services.” Furthermore, the use of “core” as opposed to “critical” helps distinguish a CCA’s obligations under Rule 17ad-26 from those under 17 CFR 242.1000 through 242.1007 (“Regulation SCI”), which addresses, in the context of clearing agencies subject to the rule, “critical systems” that support clearance and settlement. The Commission further noted that “Use of the descriptive term “core” rather than “critical” does not affect the Commission’s guidance stated in the RWP Proposing Release on identifying those services.”

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(4).

⁵ Terms not otherwise defined herein have the meaning set forth in the NSCC Rules (the “Rules”), available at www.dtcc.com/legal/rules-and-procedures.

⁶ Covered Clearing Agency Resilience and Recovery and Orderly Wind-down Plan, Exchange Act Release No. 101446 (Oct. 25, 2024), 89 FR 91000 (Nov. 18, 2024) (S7-10-23).

references to “Non-Critical Services” with “Non-Core Services.”

(ii) Proposal To Modify the Defined Terms “Recovery Plan” and “Wind-Down Plan”

For purposes of consistency with SEC Rule 17ad-26(b),¹² NSCC is proposing to capitalize references to the terms “Recovery” and “Orderly Wind-down,” and add an associated reference to the definition of these terms as set forth under SEC Rule 17ad-26(b)¹³ within the definitions of “Recovery Plan” and “Wind-down Plan” in NSCC Rule 42.

B. Implementation of the Proposal

As noted above, the principal purpose of the proposed rule change is to revise certain defined terms and make related technical changes to NSCC Rule 42 (Wind-down of the Corporation) to align with Exchange Act Rule 17ad-26. This will help to facilitate implementation of certain aspects of the RWP in a manner consistent with SEC Rule 17ad-26 and the amended RWP recently approved by the Commission.¹⁴ Based on the compliance date of SEC Rule 17ad-26 that was established by the Commission, the proposed rule change would become operative on December 15, 2025.¹⁵

2. Statutory Basis

NSCC believes that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, NSCC believes that the proposed rule change

is consistent with Section 17A(b)(3)(F) of the Act,¹⁶ Rule 17ad-22(e)(3)(ii) under the Act,¹⁷ and Rule 17ad-26 under the Act¹⁸ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the NSCC Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.¹⁹ The proposed rule change would help to ensure that the Rules are accurate and clear to participants in the event that the RWP is ever needed to be implemented by NSCC. When participants better understand their rights and obligations regarding the Rules, such participants are more likely to act in accordance with the Rules, which NSCC believes would promote the prompt and accurate clearance and settlement of securities transactions. As such, NSCC believes that the proposed changes would be consistent with Section 17A(b)(3)(F) of the Act.²⁰ Further, by providing clarity on the Rules covering an NSCC recovery and orderly wind-down, the proposed rule change would help ensure the continuity of NSCC’s core functions for the markets served by NSCC, and thereby promote the prompt and accurate clearance and settlement of securities transactions.

Rule 17ad-22(e)(3)(ii) under the Act requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.²¹ By ensuring that defined terms in the relevant Rules are consistent with how such terms are defined under Rule 17ad-26 and how they are referred to in the Plan, NSCC believes that the proposed rule change is designed to support the maintenance of the and, as such, meets the requirements of Rule 17ad-22(e)(3)(ii)

under the Act. Therefore, the proposed changes would help NSCC to maintain the Plan in a way that continues to be consistent with the requirements of Rule 17ad-22(e)(3)(ii).²²

In addition to the requirements covering elements to be included in the recovery and wind-down plans of covered clearing agencies, SEC Rule 17ad-26 includes certain associated new defined terms.²³ The proposed rule change would revise certain defined terms and make related technical changes to the applicable Rules to align with SEC Rule 17ad-26. By doing so, NSCC believes that the proposed rule change would help NSCC maintain the Plan and the Rules in a way that is consistent with Rule 17ad-26.²⁴

(B) Clearing Agency’s Statement on Burden on Competition

NSCC does not believe the proposed rule changes to revise certain defined terms and make related technical changes to align with SEC Rule 17ad-26 promulgated by the Securities and Exchange Commission would impact competition. The proposed rule changes would help to ensure that the Rules remain clear and accurate. In addition, the changes would facilitate participants understanding of the Rules and their obligations thereunder. These changes would not affect NSCC’s operations or the rights and obligations of the membership. As such, NSCC believes the proposed rule changes would not have any impact on competition.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b-4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b-4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission’s instructions on

¹² *Id.*

¹³ *Id.* Pursuant to SEC Rule 17ad-26(b), “Recovery” means the actions of a covered clearing agency, consistent with its rules, procedures, and other ex ante contractual arrangements, to address any uncovered loss, liquidity shortfall, or capital inadequacy, whether arising from participant default or other causes (such as business, operational, or other structural weaknesses), including actions to replenish any depleted prefunded financial resources and liquidity arrangements, as necessary to maintain the covered clearing agency’s viability as a going concern and to continue its provision of core services, as identified by the covered clearing agency pursuant to paragraph (a)(1) of this section.” The term “Orderly wind-down” means the actions of a covered clearing agency to effect the permanent cessation, sale, or transfer of one or more of its core services, as identified by the covered clearing agency pursuant to paragraph (a)(1) of this section, in a manner that would not increase the risk of significant liquidity, credit, or operational problems spreading among financial institutions or markets and thereby threaten the stability of the U.S. financial system.

¹⁴ *Id.*

¹⁵ *Id.* As set forth in the Adopting Release, “[. . .] (2) the proposed rule changes and Advance Notices must be effective by December 15, 2025. These compliance dates provide sufficient time for CCAs to consider changes to their rules, policies, and procedures necessary to ensure consistency with the rules amended and adopted in this release [. . .].”

¹⁶ 15 U.S.C. 78q-1(b)(3)(F).

¹⁷ See 17 CFR 240.17ad-22(e)(3)(ii). NSCC is a “covered clearing agency” as defined in Rule 17ad-22(a)(5) under the Act and must comply with paragraph (e) of Rule 17ad-22. In 2012, NSCC was designated a Systemically Important Financial Market Utility by the Financial Stability Oversight Council.

¹⁸ *Supra* note 6.

¹⁹ 15 U.S.C. 78q-1(b)(3)(F).

²⁰ *Id.*

²¹ *Supra* note 17.

²² *Supra* note 6.

²³ *Id.*

²⁴ *Id.*

how to submit comments, *available at* www.sec.gov/rules-regulations/how-submit-comment. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at tradingandmarkets@sec.gov or 202-551-5777.

NSCC reserves the right to not respond to comments 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)²⁵ of the Act and paragraph (f) of Rule 19b-4 thereunder.²⁶ 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 will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NSCC-2025-015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR-NSCC-2025-015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying

at the principal office of NSCC and on DTCC's website (<https://dtcc.com/legal/sec-rule-filings.aspx>). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NSCC-2025-015 and should be submitted on or before December 19, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁷

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21399 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104246; File No. SR-MEMX-2025-32]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposal To Amend Rule 13.4(a) To Reflect the Operation of 24X Exchange

November 24, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 19, 2025, MEMX LLC ("MEMX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend Rule 13.4(a) regarding the public disclosure of the sources of data that the Exchange utilizes when performing: (i) order handling; (ii) order routing; (iii)

order execution; and (iv) related compliance processes to reflect the operation of the 24X National Exchange LLC ("24X Exchange") as a registered national securities exchange⁵ beginning on October 14, 2025.⁶ The text of the proposed rule change is provided in Exhibit 5 and is available on the Exchange's website at <https://info.memxtrading.com/regulation/rules-and-filings/>.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13.4(a) (Usage of Data Feeds) regarding the public disclosure of the sources of data that the Exchange utilizes when performing: (i) order handling; (ii) order routing; (iii) order execution; and (iv) related compliance processes to reflect the operation of the 24X Exchange as a registered national securities exchange. On November 27, 2024, the Commission approved 24X Exchange's application to register as a national securities exchange.⁷ As part of its transition to exchange status, 24X Exchange announced that it plans to launch the first stage of its exchange on October 14, 2025.⁸ The Exchange, therefore, proposes to update Rule 13.4(a) regarding the public disclosure of the sources of data that the Exchange utilizes when performing: (i) order handling; (ii) order routing; (iii) order execution; and (iv) related compliance processes to reflect the operation of 24X

⁵ See Securities Exchange Act Release No. 101777 (November 27, 2024), 89 FR 97092 (December 6, 2024).

⁶ See Launch Date for First Stage of 24X National Exchange Moved to October 14, 2025 (dated September 26, 2025) at: <https://www.prnewswire.com/news-releases/launch-date-for-first-stage-of-24x-national-exchange-moved-to-october-14-2025-302568512.html>.

⁷ See *supra* note 5.

⁸ See *supra* note 6.

²⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4.

²⁵ 15 U.S.C. 78s(b)(3)(A).

²⁶ 17 CFR 240.19b-4(f).

Exchange as a registered national securities exchange beginning on October 14, 2025. Specifically, the Exchange proposes to amend Rule 13.4(a) to include 24X Exchange by stating it will utilize 24X Exchange market data from the Consolidated Quotation System (“CQS”)/UTP Quotation Data Feed (“UQDF”) for purposes of order handling, routing, execution, and related compliance processes.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ requirements that the rules of an exchange be 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.

In particular, the Exchange believes that the proposal to update Rule 13.4(a) to include 24X Exchange will ensure that the Rule publicly states on a market-by-market basis all of the specific network processor and proprietary data feeds that the Exchange utilizes for the handling, routing, and execution of orders, and for performing the regulatory compliance checks related to each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest because it provides additional specificity, clarity and transparency.

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. To the contrary, the Exchange believes the proposal would enhance competition because including all of the exchanges enhances transparency and enables investors to better assess the quality of

the Exchange's execution and routing services.

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) of the Act¹¹ and Rule 19b-4(f)(6)¹² thereunder. Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹³ and Rule 19b-4(f)(6)¹⁴ thereunder.

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹⁵ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹⁶ permits the Commission to 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 proposed rule change may become operative immediately. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any novel regulatory issues and waiver will allow the Exchange to provide clarity to market participants with respect to the specific network processor and proprietary data feeds that the Exchange utilizes for the handling, routing, and execution of orders, and for performing the regulatory compliance checks related to each of those functions for 24X. Therefore, the Commission hereby

waives the 30-day operative delay and designates the proposal operative upon filing.¹⁷

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 will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-MEMX-2025-32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-MEMX-2025-32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-MEMX-2025-32 and should be submitted on or before December 19, 2025.

¹⁷ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ 15 U.S.C. 78s(b)(3)(A).

¹² 17 CFR 240.19b-4(f)(6).

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 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 its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁵ 17 CFR 240.19b-4(f)(6).

¹⁶ 17 CFR 240.19b-4(f)(6)(iii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Stephanie J. Fouse,
Assistant Secretary.

[FR Doc. 2025–21395 Filed 11–26–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104247; File No. SR–CboeBZX–2025–076]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To Adopt New Rule 14.11(n) To Permit the Generic Listing and Trading of Class Exchange-Traded Fund Shares

November 24, 2025.

On June 2, 2025, Cboe BZX Exchange, Inc. (“Exchange” or “BZX”) 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 new BZX Rule 14.11(n) to permit the generic listing and trading of Class Exchange-Traded Fund Shares. The proposed rule change was published for comment in the **Federal Register** on June 10, 2025.³

On July 14, 2025, pursuant to 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 August 26, 2025, the Exchange filed Amendment No. 1 to the proposed rule change, and on August 27, 2025, the Commission issued notice of filing of Amendment No. 1 to the proposed rule change and instituted proceedings pursuant to Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.⁷ On November 19, 2025, the Exchange filed Amendment No. 2, which amended and replaced the

proposed rule change, as modified by Amendment No. 1, in its entirety.⁸ The Commission has received no comments regarding the proposed rule change.

The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 2, from interested persons and to grant approval of the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

I. The Exchange’s Description of the Proposal, as Modified by Amendment No. 2

The Exchange is filing a proposed rule change to adopt Rule 14.11(n) to permit the generic listing and trading of Class Exchange-Traded Fund Shares. The Exchange is also proposing to make conforming changes to the Exchange’s definitions, corporate governance requirements under Rule 14.10(e), and other provisions of Rule 14.11 in order to accommodate the proposed listing of Class Exchange-Traded Fund Shares. 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://markets.cboe.com/us/equities/regulation/rule_filings/bzx/) and at the Exchange’s Office of the Secretary.

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

This Amendment No. 2 to SR–CboeBZX–2025–076 amends and replaces in its entirety the proposal as originally submitted on June 2, 2025, and as amended by Amendment No. 1 on August 26, 2025. The Exchange

submits this Amendment No. 2 in order to clarify certain points and add additional details to the proposal.

The Exchange proposes to adopt new Rule 14.11(n) for the purpose of permitting the generic listing and trading, or trading pursuant to unlisted trading privileges, of Class Exchange-Traded Fund (“ETF”) Shares.⁹ The Exchange is also proposing to make conforming changes to the Exchange’s definitions, corporate governance requirements under Rule 14.10(e), and other provisions of Rule 14.11 in order to accommodate the proposed listing of Class ETF Shares.

Consistent with ETF Shares listed under the generic listing standards in Rule 14.11(l), Class ETF Shares would be permitted to be listed and traded on the Exchange without prior Commission approval order or notice of effectiveness pursuant to Section 19(b) of the Act.¹⁰

Background

There are numerous applications for exemptive relief for Class ETF Shares currently before the Commission ¹¹ that

⁹ The Exchange notes that it had previously submitted a version of this filing on April 15, 2024. See Securities Exchange Act Release No. 34–100034 (May 1, 2024) 89 FR 35255 (SR–CboeBZX–2024–026). On November 8, 2024, that filing was withdrawn and the Exchange submitted another filing. See Securities Exchange Act Release No. 101655 (November 25, 2024) 89 FR 92989 (SR–CboeBZX–2024–112). On June 2, 2025, the Exchange withdrew that filing and submitted this proposal.

¹⁰ Rule 19b–4(e)(1) provides that the listing and trading of a new derivative securities product by a self-regulatory organization (“SRO”) is not deemed a proposed rule change, pursuant to paragraph (c)(1) of Rule 19b–4, if the Commission has approved, pursuant to Section 19(b) of the Act, the SRO’s trading rules, procedures and listing standards for the product class that would include the new derivative securities product and the SRO has a surveillance program for the product class. As contemplated by this Rule 14.11(n), the Exchange proposes new Rule 14.11(n) to establish generic listing standards for Class ETF Shares (as defined herein) of the ETF Class (as defined herein) that would be required to operate as an ETF pursuant to the Multi-Class Fund Exemptive Relief (as defined herein) and be in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act of 1940 (the “Investment Company Act”), except as noted in the Multi-Class Fund Exemptive Relief. Class ETF Shares listed under proposed Rule 14.11(n) would therefore not need a separate proposed rule change pursuant to Rule 19b–4 before it can be listed and traded on the Exchange.

¹¹ See e.g., DFA Investment Dimensions Group Inc. and Dimensional Investment Group Inc., (amendment filed March 31, 2025); F/m Investments LLC (amendment filed April 10, 2025); Fidelity Hastings Street Trust and Fidelity Management & Research Company (amendment filed April 11, 2025); Morgan Stanley Institutional Fund Trust and Morgan Stanley Investment Management Inc. (amendment filed April 11, 2025); BlackRock Funds (amendment filed April 15, 2025); Guinness Atkinson Funds (amendment filed April 17, 2025); Metropolitan West Funds, TCW ETF Trust, and TCW Funds, Inc. (amendment filed April

¹⁸ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 103188 (June 4, 2025), 90 FR 24457.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 103453, 90 FR 33445 (July 17, 2025).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 103789, 90 FR 42480 (Sept. 2, 2025).

⁸ Amendment No. 2 to the proposed rule change is available on the Commission’s website at: <https://www.sec.gov/comments/sr-cboebzx-2025-076/srcboebzx2025076-677447-2073334.pdf>.

request exemptive relief similar to that previously granted to other funds.¹² This proposal would provide for the “generic” listing and/or trading of Class ETF Shares under proposed Rule 14.11(n) on the Exchange.

Starting in 2000, the Commission began granting limited relief for The Vanguard Group, Inc. (“Vanguard”) to offer certain index-based open-end management investment companies with Class ETF Shares.¹³ After this relief was granted, there was limited public discourse about Class ETF Shares until 2019, when the prospect of providing blanket exemptive relief to Class ETF Shares was addressed in the Commission’s adoption of Rule 6c–11 (the “ETF Rule”)¹⁴ under the Investment Company Act of 1940 (the “Investment Company Act”). The ETF Rule permits ETFs that satisfy certain conditions to operate without the expense or delay of obtaining an exemptive order. However, the ETF Rule did not provide blanket exemptive relief to allow for Class ETF Shares as part of the final rule. Instead, the Commission concluded that Class ETF Shares should request relief through the exemptive application process so that the Commission may assess all relevant policy considerations in the context of the facts and circumstances of particular applicants. The Exchange adopted Rule 14.11(l)¹⁵ shortly after the implementation of the ETF Rule and, because there were no exemptive

applications before the Commission, the Exchange did not propose to include any language comparable to what is being proposed herein.

As noted above, a number of applications for exemptive relief to permit the applicable fund to offer Class ETF Shares (the “Applications”) have been submitted to the Commission starting in early 2023. In general, the Applications state that the ability of a fund to offer Class ETF Shares, *i.e.*, a fund offering both a class of mutual fund shares and a class of shares that are exchange traded, could be beneficial to the fund and to shareholders of each type of class for various reasons, including more efficient portfolio management, better secondary market trading opportunities, and cost efficiencies, among others.¹⁶ The Commission has granted by order specific exemptive relief (“Multi-Class Fund Exemptive Relief”) under the Investment Company Act on November 17, 2025, that permits, subject to certain conditions and requirements, a Multi-Class Fund (as defined below) to issue Class ETF Shares (as defined below) and one or more classes of shares that are not exchange-traded, among other things.¹⁷

Proposal

Proposed Rule 14.11(n)(1) provides that the Exchange will consider for trading, whether by listing or pursuant to unlisted trading privileges, Class ETF Shares that meet the criteria of this Rule.¹⁸

¹⁶ *Supra* note 11.

¹⁷ See Investment Company Act Release No. 35786 (November 17, 2025) (In the Matter of DFA Investment Dimensions Group Inc., Dimensional Investment Group Inc., Dimensional ETF Trust and Dimensional Fund Advisors LP) (File No. 812–15484).

¹⁸ To the extent that Class ETF Shares do not satisfy one or more of the criteria in proposed Rule 14.11(n), the Exchange may file a separate proposal under Section 19(b) of the Act in order to list such securities on the Exchange. Any of the statements or representations in that proposal regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index, reference asset, and intraday indicative values (as applicable), or the applicability of Exchange listing rules specified in any filing to list such Class ETF Shares shall constitute continued listing requirements for the Class ETF Shares. Further, in the event that Class ETF Shares become listed under proposed Rule 14.11(n) and subsequently can no longer satisfy the requirements of proposed Rule 14.11(n), such Class ETF Shares may be listed as a series of Index Fund Shares under Rule 14.11(c) or Managed Fund Shares under Rule 14.11(i), as applicable, as long as the Class ETF Shares meets all listing requirements applicable under the alternate listing rule. If the Class ETF Shares do change listing standards, the Exchange would have to comply with all of the requirements of Rule 19b–4(e) with respect to such Class ETF Shares.

Proposed Rule 14.11(n)(2) provides that the proposed rule would be applicable only to Class ETF Shares. Except to the extent inconsistent with this Rule 14.11(n), or unless the context otherwise requires, the rules and procedures of the Board of Directors shall be applicable to the trading on the Exchange of such securities. Class ETF Shares are included within the definition of “security” or “securities” as such terms are used in the Rules of the Exchange.

Proposed Rule 14.11(n)(2) further provides that: (A) transactions in Class ETF Shares will occur throughout the Exchange’s trading hours; and (B) the Exchange will implement and maintain written surveillance procedures for Class ETF Shares.

Proposed Rule 14.11(n)(3)(A) provides that the term “Class ETF Shares” shall mean shares of the ETF Class¹⁹ issued by a Multi-Class Fund.²⁰

Proposed Rule 14.11(n)(3)(B) provides that the term “ETF Class” means the class of exchange-traded shares of a Multi-Class Fund that (i) operates as an exchange-traded fund pursuant to exemptive relief granted by order under the Investment Company Act (“Multi-Class Fund Exemptive Relief”), and (ii) is in compliance with the requirements of proposed Rules 14.11(n)(4)(b) and 14.11(n)(4)(B)(i)(a)(2), discussed below, on an initial and continued listing basis.

Proposed Rule 14.11(n)(3)(C) provides that the term “Multi-Class Fund” means a registered open-end management company that (i) pursuant to Multi-Class Fund Exemptive Relief, issues Class ETF Shares and one or more classes of shares that are not exchange-traded, and (ii) is in compliance with the conditions and requirements of the Multi-Class Fund Exemptive Relief.

Proposed Rule 14.11(n)(3)(D) provides that the term “Reporting Authority” in respect of a particular Multi-Class Fund means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists Class ETF Shares (if the Exchange is trading such securities pursuant to unlisted trading privileges) as the official source for calculating and reporting information relating to such Multi-Class Fund, including, but not limited to, the amount of any dividend equivalent payment or cash distribution to holders of Class ETF Shares, net asset value, index or portfolio value, the current value of the portfolio of securities required to be deposited in connection with the issuance of Class ETF Shares, or other information

¹⁹ See proposed Rule 14.11(n)(3)(B).

²⁰ See proposed Rule 14.11(n)(3)(C).

22, 2025); and Northern Funds and Northern Trust Investments, Inc. (amendment filed May 2, 2025).

¹² *Infra* note 13.

¹³ See Vanguard Index Funds, Investment Company Act Release Nos. 24680 (Oct. 6, 2000) (notice) and 24789 (Dec. 12, 2000) (order). The Commission itself, as opposed to the Commission staff acting under delegated authority, considered the original Vanguard application and determined that the relief was appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Investment Company Act. In the process of granting the order, the Commission also considered and denied a hearing request on the original application, as reflected in the final Commission order. See also the Vanguard Group, Inc., Investment Company Act Release Nos. 26282 (Dec. 2, 2003) (notice) and 26317 (Dec. 30, 2003) (order); Vanguard International Equity Index Funds, Investment Company Act Release Nos. 26246 (Nov. 3, 2003) (notice) and 26281 (Dec. 1, 2003) (order); Vanguard Bond Index Funds, Investment Company Act Release Nos. 27750 (Mar. 9, 2007) (notice) and 27773 (April 2, 2007) (order) (collectively referred to as the “Vanguard Orders”).

¹⁴ See Securities Exchange Act Release No. 33–10695 (September 25, 2019) 84 FR 57162 (October 24, 2019) (the “ETF Rule Adopting Release”).

¹⁵ See Securities Exchange Act No. 88566 (April 6, 2020) 85 FR 20312 (April 10, 2020) (SR–CboeBZX–2019–097) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To Adopt BZX Rule 14.11(l) Governing the Listing and Trading of Exchange-Traded Fund Shares).

relating to the issuance, redemption or trading of Class ETF Shares. A Multi-Class Fund may have more than one Reporting Authority, each having different functions.

Proposed Rule 14.11(n)(4) provides that the Exchange may approve Class ETF Shares of a Multi-Class Fund for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b-4(e) under the Act, provided that: (a) the Multi-Class Fund is eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (b) the ETF Class is in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (c) the ETF Class and the Multi-Class Fund each satisfies the requirements of this Rule 14.11(n), as applicable, on an initial and continued listing basis.

Proposed Rule 14.11(n)(4)(A) provides that the requirements of paragraph (4) of this Rule must be satisfied by the Multi-Class Fund issuing the Class ETF Shares on an initial and continued listing basis. The Multi-Class Fund with respect to such Class ETF Shares must also satisfy the following criteria on an initial and, except for sub-paragraph (i) below, continued listing basis. Further, proposed Rule 14.11(n)(4)(A) provides that: (i) for each Multi-Class Fund, the Exchange will establish a minimum number of Class ETF Shares required to be outstanding at the time of commencement of trading on the Exchange; (ii) if an index underlying a Multi-Class Fund is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a “fire wall” around the personnel who have access to information concerning changes and adjustments to the index, and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to an actively managed Multi-Class Fund is affiliated with a broker-dealer, such investment adviser shall erect and maintain a “fire wall” between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Multi-Class Fund’s portfolio; and (iii) any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a Multi-Class Fund, must implement and maintain, or be

subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. For actively managed Multi-Class Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable portfolio.

Proposed Rule 14.11(n)(4)(B) provides that Class ETF Shares of each Multi-Class Fund will be listed and traded on the Exchange subject to application of the continued listing criteria therein. Proposed Rule 14.11(n)(4)(B)(i) provides that the Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 14.12 for, Class ETF Shares under any of the following circumstances: (a) if the Exchange becomes aware that, with respect to the Class ETF Shares: (1) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (2) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (b) if any of the other listing requirements set forth in this Rule are not continuously maintained; (c) if, following the initial twelve-month period after commencement of trading on the Exchange of the Class ETF Shares, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days; or (d) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.11(n)(4)(B)(ii) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing.

Proposed Rule 14.11(n)(5) provides that neither the Exchange, the Reporting Authority, nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the Multi-Class Fund in connection with the issuance of Class ETF Shares; the amount of any dividend equivalent

payment or cash distribution to holders of Class ETF Shares; net asset value; or other information relating to the purchase, redemption, or trading of Class ETF Shares, resulting from any negligent act or omission by the Exchange, the Reporting Authority, or any agent of the Exchange, or any act, condition, or cause beyond the reasonable control of the Exchange, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

The Exchange is also proposing to make corresponding amendments to include Class ETF Shares in other Exchange rules, which are intended to align the treatment of the proposed products with how other open-end management investment company shares (e.g., ETF Shares, Index Fund Shares, and Managed Fund Shares) are treated under the Exchange’s rules. First, the Exchange is proposing to add Class ETF Shares to the definition of UTP Security in Rule 1.5(ee) and to amend Rule 14.11(c)(3)(A)(i)(a) in order to include Class ETF Shares in the definition of Derivative Securities Products. The Exchange believes this is appropriate to ensure that Class ETF Shares are treated consistently with other open-end management investment company shares listed on the Exchange such as ETF Shares, Index Funds Shares, and Managed Fund Shares.

Second, the Exchange proposes to amend Rule 14.10(e)(1)(E)(ii) to exempt Class ETF Shares from the requirements of Rule 14.10(i)(1) in connection with the acquisition of the stock or assets of an affiliated registered investment company in a transaction that complies with Rule 17a-8 under the Investment Company Act and does not otherwise require shareholder approval under the Investment Company Act and the rules thereunder or any other Exchange rule.²¹

²¹ Rule 14.10(1)(F) provides that issuers whose only securities listed on the Exchange are non-voting preferred securities, debt securities or Derivative Securities, are exempt from the requirements relating to Independent Directors (as set forth in Rule 14.10(c)(2)), Compensation Committees (as set forth in Rule 14.10(c)(4)), Director Nominations (as set forth in Rule 14.10(c)(5)), Code of Conduct (as set forth in Rule 14.10(d)), and Meetings of Shareholders (as set forth in Rule 14.10(f)). In addition, these issuers are exempt from the requirements relating to Audit Committees (as set forth in Rule 14.10(c)(3)), except for the applicable requirements of SEC Rule 10A-

Third, the Exchange proposes to amend the definition of “Derivative Securities” in Rule 14.10(e)(1)(F)(ii) to add Class ETF Shares so the exclusions applicable to Derivative Securities in Rule 14.10 will also apply to Class ETF Shares. The Exchange believes this is appropriate to ensure that Class ETF Shares are treated consistently with other open-end management investment company shares listed on the Exchange such as ETF Shares, Index Fund Shares, and Managed Fund Shares. In addition, these issuers are exempt from the requirements relating to Audit Committees (as set forth in Rule 14.10(c)(3)), except for the applicable requirements of SEC Rule 10A-3.²²

Discussion

Proposed Rule 14.11(n) is based on Rule 14.11(l) related to the listing and trading of ETF Shares on the Exchange, which are issued under the Investment Company Act and qualify as ETF Shares under Rule 6c-11. ETF Shares are similar to Class ETF Shares because the ETF Class is required to operate as an ETF pursuant to the Multi-Class Fund Exemptive Relief and be in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act (except as noted in the Multi-Class Fund Exemptive Relief).²³ The proposed Class ETF Shares generic listing rules would apply only to the class of shares that are exchange-traded. Because the ETF Class would be required to comply, among other things, with the conditions and requirements of Rule 6c-11 under the Investment Company Act, similar to ETF Shares under Rule 14.11(l), the Exchange believes that using Rule 14.11(l) as the basis for proposed Rule 14.11(n) is appropriate.

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices because the Exchange will perform ongoing surveillance of Class ETF Shares listed on the Exchange in order to ensure that (a) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief; (b) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class

Fund Exemptive Relief; and (c) the ETF Class and the Multi-Class Fund each satisfies the requirements of Rule 14.11(n), as applicable, on an initial and continued basis. The Exchange believes that the manipulation concerns are mitigated by a combination of the Exchange’s surveillance procedures, the Exchange’s ability to halt trading under proposed Rule 14.11(n)(4)(B)(ii), and the Exchange’s ability to suspend trading and commence delisting proceedings under proposed Rule 14.11(n)(4)(B)(i). The Exchange will halt trading in the Class ETF Shares under the conditions specified in Rule 11.18, “Trading Halts Due to Extraordinary Market Volatility.” The Exchange also believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that have come from Rule 6c-11, specifically the additional flexibility provided through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c-11.²⁴ The Exchange also notes that there are firewall and other information barrier restrictions in place in the proposed rule text.²⁵ The Exchange believes that the combination of these factors will act to keep Class ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of Class ETF Shares on the Exchange. The Exchange will monitor for compliance to ensure that (i) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is in otherwise compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of 14.11(n), as applicable, on an initial and continuing basis. Specifically, the Exchange will review the website of Class ETF Shares listed on the Exchange in order to ensure that the requirements of Rule 6c-11 are being met. The Exchange will also employ numerous intraday alerts that will notify Exchange personnel of trading activity throughout

the day that is potentially indicative of certain disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. As a backstop to the surveillances described above, the Exchange also notes that Rule 14.11(a) would require an issuer of Class ETF Shares to notify the Exchange of any failure to comply with the requirements of proposed Rule 14.11(n), the Multi-Class Fund Exemptive Relief, or Rule 6c-11 under the Investment Company Act.

The Exchange may suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable.²⁶ The Exchange also notes that Rule 14.11(a) requires any issuer to provide the Exchange with prompt notification after it becomes aware that (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or otherwise no longer complies with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class is no longer compliant with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, or (iii) the ETF Class or the Multi-Class Fund no longer satisfies the requirements of Rule

²⁶ Specifically, proposed Rule 14.11(n)(4)(B) provides that Class ETF Shares will be listed and traded on the Exchange subject to application of proposed Rule 14.11(n)(4)(B)(i) and (ii). Proposed Rule 14.11(n)(4)(B)(i) provides that the Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 14.12 for Class ETF Shares under any of the following circumstances: (i) if the Exchange becomes aware that, with respect to the Class ETF Shares: (1) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (2) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (ii) if any of the other listing requirements set forth in this Rule are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of Class ETF Shares, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.11(n)(4)(B)(ii) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing.

3. Notwithstanding, if the issuer also lists its common stock or voting preferred stock, or their equivalent on the Exchange it will be subject to all the requirements of Exchange Rule 14.10.

²² *Id.*

²³ See *supra* note 17.

²⁴ The Exchange notes that the Commission came to a similar conclusion in several places in the ETF Rule Adopting Release. See ETF Rule Adopting Release at 15–18; 60–61; 69–70; 78–79; 82–84; and 95–96.

²⁵ See proposed Rule 14.11(n)(4)(A)(ii).

14.11(n), as applicable, on an initial and continuing basis.²⁷

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the Class ETF Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to ETF Shares, Index Fund Shares and Managed Fund Shares among other product types, to monitor trading in Class ETF Shares. The Exchange or the Financial Industry Regulatory Authority, Inc. ("FINRA"), on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the Intermarket Surveillance Group ("ISG") or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Finally, the issuer of Class ETF Shares will be required to comply with Rule 10A-3 under the Act for the initial and continued listing of Class ETF Shares, as provided under Rule 14.10(e)(1)(E).²⁸

The Exchange notes that it may consider all relevant factors in exercising its discretion to halt or suspend trading in Class ETF Shares. Trading may be halted if the circuit breaker parameters in Rule 11.18 have been reached, because of other market conditions, or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) the extent to which certain information about the Class ETF Shares that is required to be disclosed under Rule 6c-11 of the Investment Company Act is not being made available,

including specifically where the Exchange becomes aware that the net asset value or the daily portfolio disclosure with respect to Class ETF Shares is not disseminated to all market participants at the same time, it will halt trading in such securities until such time as the net asset value or the daily portfolio disclosure is available to all market participants;²⁹ (2) if an interruption to the dissemination to the value of the index or reference asset on which Class ETF Shares is based persists past the trading day in which it occurred or is no longer calculated or available; (3) trading in the securities comprising the underlying index or portfolio has been halted in the primary market(s); or (4) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. The Exchange deems Class ETF Shares to be equity securities and therefore they would be subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.³⁰

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.³¹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³² requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)³³ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that proposed Rule 14.11(n) is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading Class ETF Shares on the Exchange provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 14.11(n)(4) sets forth initial and continued listing criteria applicable to Class ETF Shares, specifically providing that the Exchange may approve Class ETF Shares for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b-4(e) under the Act, provided that: (i) the Multi-Class Fund is eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (ii) the ETF Class is in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of this Rule 14.11(n), as applicable, on an initial and continued listing basis.³⁴ The Exchange will comply with all the requirements of Rule 19b-4(e) to specifically note that such Class ETF Shares are being listed on the Exchange pursuant to Rule 14.11(n).

Proposed Rule 14.11(n)(4)(B) provides that Class ETF Shares of each Multi-Class Fund will be listed and traded on the Exchange subject to application of proposed Rules 14.11(n)(4)(B)(i) and (ii). Proposed Rule 14.11(n)(4)(B)(i) provides

³³ *Id.*

³⁴ The Exchange notes that eligibility to operate in reliance on Rule 6c-11 or any applicable exemptive relief under the Investment Company Act does not necessarily mean that an investment company would be listed on the Exchange pursuant to proposed Rule 14.11(n). To this point, an investment company that operates in reliance of exemptive relief providing for Class ETF Shares could alternatively be listed as a series of Index Fund Shares or Managed Fund Shares pursuant to Rule 14.11(c) or (i), respectively, and would be subject to all requirements under each of those rules. Further to this point, in the event that Class ETF Shares listed on the Exchange preferred to be listed as a series of Index Fund Shares or Managed Fund Shares (as applicable), nothing would preclude such security from changing to be listed as a series of Index Fund Shares or Managed Fund Shares (as applicable), as long as the security met each of the initial and continued listing obligations under the applicable rules.

²⁷ The Exchange notes that failure by an issuer to notify the Exchange of non-compliance pursuant to Rule 14.11(a) would itself be considered non-compliance with the requirements of proposed Rule 14.11(n) and would subject the Class ETF Shares to potential trading halts and the delisting process under Rule 14.12.

²⁸ See *supra* note 21. The Exchange notes that these proposed changes in Rule 14.10(e)(1)(E) would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange.

²⁹ The Exchange will obtain a representation from the issuer of Class ETF Shares that the net asset value per share will be calculated daily and made available to all market participants at the same time, and the requirements pertaining to the Multi-Class Fund Exemptive Relief and Rule 6c-11 under the Investment Company Act in proposed Rule 14.11(n) will be satisfied.

³⁰ With respect to trading in Class ETF Shares, the Exchange represents that all of the BZX Member obligations related to product description and prospectus delivery requirements will continue to apply in accordance with the Exchange Rules and federal securities laws, and the Exchange will continue to monitor its Members for compliance with such requirements, which are not changing as a result of the Multi-Class Fund Exemptive Relief order issued under the Investment Company Act.

³¹ 15 U.S.C. 78f(b).

³² 15 U.S.C. 78f(b)(5).

that the Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 14.12 for, Class ETF Shares under any of the following circumstances: (a) if the Exchange becomes aware that, with respect to the Class ETF Shares: (1) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (2) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (b) if any of the other listing requirements set forth in this Rule 14.11(n) are not continuously maintained; (c) if, following the initial twelve month period after commencement of trading on the Exchange of Class ETF Shares, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days; or (d) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. The Exchange notes that it may become aware that the issuer is no longer compliant with Rule 6c-11 or any applicable exemptive relief thereunder, as described in proposed Rule 14.11(n)(4)(B)(i)(a), as a result of either the Exchange identifying non-compliance through its own monitoring process or through notification by the issuer.

Proposed Rule 14.11(n)(4)(B)(ii) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing. The Exchange also notes that it will obtain a representation from the issuer of Class ETF Shares stating that the requirements of Rule 6c-11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied and that the issuer will notify the Exchange of any failure to do so.

The Exchange further believes that proposed Rule 14.11(n) is designed to prevent fraudulent and manipulative acts and practices because of the robust surveillances in place on the Exchange as required under proposed Rule 14.11(n)(2)(C) along with the similarities of proposed Rule 14.11(n) to the rules related to other securities that are already listed and traded on the Exchange and which would qualify as Class ETF Shares. ETF Shares are identical to Class ETF Shares except

that Class ETF Shares have received exemptive relief to operate an exchange-traded fund class in addition to classes of shares that are not exchange-traded. As such, the Exchange believes because the ETF Class would be required to comply, among other things, with the conditions and requirements of Rule 6c-11 under the Investment Company Act, similar to ETF Shares under Rule 14.11(l), the Exchange believes that using Rule 14.11(l) as the basis for proposed Rule 14.11(n) is appropriate.

The Exchange believes that the proposal is consistent with Section 6(b)(1) of the Act in that,³⁵ in addition to being designed to prevent fraudulent and manipulative acts and practices, the Exchange has the capacity to enforce proposed Rule 14.11(n) by performing ongoing surveillance of Class ETF Shares listed on the Exchange in order to ensure that (a) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (b) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (c) the ETF Class and the Multi-Class Fund each satisfies the requirements of Rule 14.11(n), as applicable, on an initial and continued basis. The Exchange believes that the manipulation concerns that such standards are intended to address are mitigated by a combination of the Exchange's surveillance procedures, the Exchange's ability to halt trading under the proposed Rule 14.11(n)(4)(B)(ii), and the Exchange's ability to suspend trading and commence delisting proceedings under proposed Rule 14.11(n)(4)(B)(i). The Exchange will also halt trading in Class ETF Shares under the conditions specified in Rule 11.18, "Trading Halts Due to Extraordinary Market Volatility." The Exchange also believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that have come from compliance with Rule 6c-11, specifically the additional flexibility provided through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c-11.³⁶ The Exchange believes that the

combination of these factors will act to keep Class ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of Class ETF Shares on the Exchange. The Exchange will monitor for compliance with Rule 6c-11 and any applicable exemptive relief in order to ensure that the continued listing standards are being met. Specifically, the Exchange plans to review the website of Class ETF Shares in order to ensure that the requirements of Rule 6c-11 are being met. The Exchange will also employ numerous intraday alerts that will notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. As a backstop to the surveillances described above, the Exchange also notes that Rule 14.11(a) would require an issuer of Class ETF Shares to notify the Exchange of any failure to comply with Rule 6c-11 or the requirements of the Multi-Class Fund Exemptive Relief under the Investment Company Act.

To the extent that any of the requirements under Rule 6c-11 or Multi-Class Fund Exemptive Relief under the Investment Company Act are not being met, the Exchange may halt trading Class ETF Shares as provided in proposed Rule 14.11(n)(4)(B)(ii).

Further, the Exchange may also suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable. As discussed above, the Exchange also notes that Rule 14.11(a) requires any issuer to provide the Exchange with prompt notification after it becomes aware of any non-compliance with proposed Rule 14.11(n), which would include any failure of the issuer to comply with Rule 6c-11 or the Multi-Class Fund Exemptive Relief under the Investment Company Act.

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the Class ETF Shares in all trading sessions and to deter and detect violations of Exchange rules. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative

³⁵ 15 U.S.C. 78f(b)(1).

³⁶ The Exchange notes that the Commission came to a similar conclusion in several places in the ETF Rule Adopting Release. See ETF Rule Adopting

products, which are currently applicable to Index Fund Shares, Managed Fund Shares and ETF Shares, among other product types, to monitor trading in Class ETF Shares. The Exchange or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a Multi-Class Fund for the Class ETF Shares reported to FINRA's TRACE. FINRA also can access data obtained from the MSRB's EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading Class ETF Shares, to the extent that the Multi-Class Fund for the Class ETF Shares holds municipal securities. Finally, as noted above, the issuer of Class ETF Shares will be required to comply with Rule 10A-3 under the Act for the initial and continued listing of Class ETF Shares, as provided under Rule 14.10(e)(1)(E).³⁷

The Exchange believes that permitting Class ETF Shares to list on the Exchange will help perfect the mechanism of a free and open market and, in general, will protect investors and the public interest in that it will permit the listing and trading of Class ETF Shares, consistent with the applicable exemptive relief, and in a manner that will benefit investors. Specifically, the Exchange believes that the relief proposed in the Applications and the expected benefits of the Class ETF Shares described above would be to the benefit of investors.

The Exchange also believes that proposed Rule 14.11(n) to explicitly provide that the initial and continued listing standards applicable to Class ETF Shares, including the suspension of trading or removal standards, are designed to promote transparency and clarity in the Exchange's Rules.

The Exchange also believes that the corresponding changes to add Class ETF Shares in the Exchange's definitions, corporate governance requirements under Rule 14.10(e), and other provisions of Rule 14.11 in order to accommodate the proposed listing of Class ETF Shares will add clarity to the Exchange's Rulebook. ETF Shares, Managed Fund Shares, and Index Fund Shares are similarly included in these provisions. Therefore, the Exchange believes these are non-substantive changes meant only to subject Class ETF Shares to the same exemptions and provisions currently applicable to ETF Shares, among other product types, so that the treatment of these open-end management investment companies is consistent under the Exchange's rules.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

A. 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. The Exchange believes the proposal, by permitting the listing and trading of Class ETF Shares under exemptive relief from the Investment Company Act and the rules and regulations thereunder, would introduce additional competition among various ETF products to the benefit of investors.

B. 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. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.³⁸ In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(5) of the Act,³⁹ which requires, among other things, that the Exchange's rules 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, in general, to protect investors and the public interest. The Commission also finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 11A(a)(1)(C)(iii) of the Act, which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.⁴⁰ In addition, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(1) of the Act,⁴¹ which requires, among other things, that the Exchange is so organized and has the capacity to be able to enforce compliance by its members and persons associated with its members with the rules of the Exchange.

The Exchange proposes to adopt new BZX Rule 14.11(n) to permit the generic listing and trading, or trading pursuant to unlisted trading privileges, of Class ETF Shares in connection with the Multi-Class Fund Exemptive Relief granted by order under the Investment Company Act.⁴² Under the proposal and pursuant to the Multi-Class Fund Exemptive Relief, a Multi-Class Fund is permitted to issue a class of shares that are exchange-traded (*i.e.*, ETF Class) and one or more classes of shares that are not exchange-traded. In accordance with the Multi-Class Fund Exemptive Relief, the ETF Class operates as an ETF in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in the Multi-Class Fund Exemptive Relief. The Exchange also proposes conforming changes to the Exchange's definitions, corporate governance requirements under BZX Rule 14.10(e), and other provisions of BZX Rule 14.11 to accommodate the proposed listing of Class ETF Shares.

A. Consistency With Section 6(b)(5) of the Act

(1) Proposed BZX Rule 14.11(n)

Proposed BZX Rule 14.11(n) is reasonably designed to help prevent fraudulent and manipulative acts and practices. Proposed BZX Rule 14.11(n) is based on BZX Rule 14.11(l), which

³⁷ The Exchange notes that these proposed changes would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange.

³⁸ In approving this proposed rule change, as modified by Amendment No. 2, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³⁹ 15 U.S.C. 78f(b)(5).

⁴⁰ See 15 U.S.C. 78k-1(a)(1)(C)(iii).

⁴¹ 15 U.S.C. 78f(b)(1).

⁴² See *supra* note 17 and accompanying text.

governs the generic listing and trading of ETF Shares on the Exchange.⁴³ Under current BZX Rule 14.11(l), ETF Shares, which must be eligible to operate in reliance on Rule 6c–11 under the Investment Company Act and must satisfy the requirements of Rule 6c–11 under the Investment Company Act on an initial and continued listing basis, are similar to Class ETF Shares because, under the proposal, the ETF Class also is required to operate as an ETF and be in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act (except as noted in the Multi-Class Fund Exemptive Relief).⁴⁴

As stated in the ETF Shares Approval Order, a central qualification for listing under the proposed rule is ongoing compliance with Rule 6c–11 under the Investment Company Act, which requires, among other things, ETFs to prominently disclose the portfolio holdings that will form the basis for each calculation of net asset value per share.⁴⁵ Because initial and ongoing compliance with Rule 6c–11 of the Investment Company Act is a condition for listing and trading Class ETF Shares on the Exchange,⁴⁶ proposed BZX Rule 14.11(n) would permit the Exchange to list and trade shares of an investment company with a fully transparent portfolio,⁴⁷ and as the Commission

previously stated for ETF Shares,⁴⁸ portfolio transparency should equally help prevent manipulation of the price of Class ETF Shares.⁴⁹ Additionally, proposed BZX Rule 14.11(n) includes requirements relating to fire walls and procedures to prevent the use and dissemination of material, non-public information regarding the applicable Multi-Class Fund index and portfolio,⁵⁰ all such requirements of which are substantively identical to those applicable to ETF Shares under BZX Rule 14.11(l) and are designed to prevent fraudulent and manipulative acts and practices.⁵¹ Certain of these

when deciding whether to invest in ETFs generally or in a particular ETF. See ETF Rule Adopting Release, *supra* note 14, 84 FR at 57166.

⁴⁸ See ETF Shares Approval Order, *supra* note 43, 85 FR at 20320 (concluding that because initial and ongoing compliance with Rule 6c–11 of the Investment Company Act is a condition for listing and trading on the Exchange, the proposed rule would permit the listing and trading of shares of an investment company with a fully transparent portfolio, and the Commission believes that portfolio transparency should help prevent manipulation of the price of ETF Shares).

⁴⁹ See ETF Rule Adopting Release, *supra* note 14, 84 FR at 57169 (concluding that portfolio transparency combined with existing requirements should be sufficient to protect against certain abuses).

⁵⁰ For example, proposed BZX Rule 14.11(n)(4)(A)(ii) provides that if an index underlying a Multi-Class Fund is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a “fire wall” around the personnel who have access to information concerning changes and adjustments to the index, and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. Proposed BZX Rule 14.11(n)(4)(A)(ii) further states that if the investment adviser to an actively managed Multi-Class Fund is affiliated with a broker-dealer, such investment adviser shall erect and maintain a “fire wall” between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Multi-Class Fund’s portfolio. Proposed BZX Rule 14.11(n)(4)(A)(iii) requires that any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a Multi-Class Fund, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable index. For actively managed Multi-Class Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable portfolio. See generally proposed BZX Rule 14.11(n)(4)(A). Compare proposed BZX Rule 14.11(n)(4)(A) (encompassing the initial and continued listing requirements for Class ETF Shares) with BZX Rule 14.11(l)(4)(A) (encompassing the initial and continued listing requirements for ETF Shares).

⁵¹ In adopting Rule 6c–11 under the Investment Company Act, the Commission stated that the safeguards in the existing regulatory regime adequately address “special concerns that self-indexed ETFs present, including the potential ability of an affiliated index provider to manipulate an underlying index to the benefit or detriment of a self-indexed ETF.” See ETF Rule Adopting

requirements relating to such fire walls and procedures apply in addition to what is already required under the Act and the Investment Company Act and respective rules and regulations thereunder, and such requirements collectively provide additional protections against the potential misuse of material, non-public information.⁵² The Commission concludes that the proposed requirements relating to such fire walls and procedures, combined with Multi-Class Fund portfolio transparency with respect to the ETF Class and the existing requirements under the Act and Investment Company Act, should help to protect against fraudulent and manipulative acts and practices under Section 6(b)(5) of the Act.⁵³

Proposed BZX Rule 14.11(n)(2)(B) requires that the Exchange implement and maintain written surveillance procedures for Class ETF Shares. The Exchange represents that it will utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to ETF Shares, among other product types, to monitor trading in Class ETF Shares, and further represents that its surveillance procedures are adequate to (a) properly monitor the trading of the Class ETF Shares during all trading sessions and (b) deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange also represents that the Exchange, or FINRA on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive

Release, *supra* note 14, 84 FR at 57168. See also ETF Shares Approval Order, *supra* note 43, 85 FR at 20320 (concluding that the requirements of BZX Rule 14.11(l), which includes provisions relating to fire walls and procedures to prevent the use and dissemination of material, non-public information regarding the applicable ETF index and portfolio for ETF Shares, are designed to prevent fraudulent and manipulative acts and practices).

⁵² See ETF Shares Approval Order, *supra* note 43, 85 FR at 20320 (stating that the requirements for ETF Shares relating to fire walls and procedures, which are substantively identical to BZX’s rules governing the listing and trading of index-based and actively managed ETFs, apply in addition to what is already required under the Act and the Investment Company Act and respective rules and regulations thereunder, and that such requirements collectively provide additional protections against the potential misuse of material, non-public information).

⁵³ See *id.* (“Therefore, the Commission concludes that the proposed requirements relating to such fire walls and procedures, combined with ETF portfolio transparency and the existing requirements under the Act and [Investment Company Act], should help to protect against fraudulent and manipulative acts and practices under Section 6(b)(5) of the Act.”).

⁴³ See BZX Rule 14.11(l). See also *supra* note 15 and accompanying text; Securities Exchange Act Release No. 88566 (Apr. 6, 2020), 85 FR 20312 (Apr. 10, 2020) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To Adopt BZX Rule 14.11(l) Governing the Listing and Trading of Exchange-Traded Fund Shares) (“ETF Shares Approval Order”).

⁴⁴ The Exchange represents that the proposed Class ETF Shares generic listing rules apply only to the class of shares (ETF Class) that are exchange-traded.

⁴⁵ See ETF Shares Approval Order, *supra* note 43, 85 FR at 20320. See also ETF Rule Adopting Release, *supra* note 14, 84 FR at 57180–81.

⁴⁶ See proposed BZX Rules 14.11(n)(4)(b) (“The Exchange may approve Class ETF Shares of a Multi-Class Fund for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b–4(e) under the Act, provided that . . . the ETF Class is in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act of 1940, except as noted in such Multi-Class Fund Exemptive Relief”) and 14.11(n)(4)(B)(i)(a)(2) (“The Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 14.12 for, Class ETF Shares . . . if the Exchange becomes aware that, with respect to the Class ETF Shares . . . the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act of 1940, except as noted in such Multi-Class Fund Exemptive Relief”).

⁴⁷ The Commission stated that, with respect to ETF portfolio transparency, the disclosures are designed to promote an effective arbitrage mechanism and inform investors about the risks of deviation between market price and net asset value

surveillance sharing agreement. The Exchange also may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by the Multi-Class Fund for the Class ETF Shares reported to TRACE. FINRA also can access data obtained from the EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in Class ETF Shares, to the extent that the Multi-Class Fund for the Class ETF Shares holds municipal securities. The Exchange states that BZX Rule 14.11(a) requires any issuer to provide the Exchange with prompt notification after it becomes aware that (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or otherwise no longer complies with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class is no longer compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, or (iii) the ETF Class or the Multi-Class Fund no longer satisfies the requirements of Rule 14.11(n), as applicable, on an initial and continuing basis.⁵⁴ The Exchange further represents that it will obtain a representation from the issuer of Class ETF Shares stating that the requirements of Rule 6c–11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied and that the issuer will notify the Exchange of any failure to do so.

Consistent with the requirement of Section 6(b)(5) of the Act⁵⁵ that the Exchange's rules be designed to remove impediments to and perfect the mechanism of a free and open market, the Exchange's rules regarding trading halts will help to ensure the maintenance of fair and orderly markets for Class ETF Shares. Specifically, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in Class ETF

Shares. The Exchange states that trading in Class ETF Shares may be halted if the circuit breaker parameters in BZX Rule 11.18 have been reached, because of other market conditions, or for reasons that, in the view of the Exchange, make trading in the Class ETF Shares inadvisable. According to the Exchange, the reasons to halt trading may include: (1) the extent to which certain information about the Class ETF Shares that is required to be disclosed pursuant to Rule 6c–11 under the Investment Company Act is not being made available;⁵⁶ (2) if an interruption to the dissemination to the value of the index or reference asset on which the Class ETF Shares is based persists past the trading day in which it occurred or is no longer calculated or available; (3) trading in the securities comprising the underlying index or portfolio has been halted in the primary market(s); or (4) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. As the Exchange further represents in the proposal, if the Exchange becomes aware that the net asset value or the daily portfolio disclosure with respect to the Class ETF Shares is not disseminated to all market participants at the same time, it will halt trading in the Class ETF Shares until such time as the net asset value or the daily portfolio disclosure is available to all market participants.⁵⁷ The Exchange represents that it may suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable.⁵⁸

The Commission also finds that, consistent with Section 11A(a)(1)(C)(iii) of the Act,⁵⁹ the proposed rule change, as modified by Amendment No. 2, is reasonably designed to promote fair disclosure of information that may be necessary to price the Class ETF Shares appropriately, to prevent trading when a reasonable degree of transparency cannot be assured, to safeguard material non-public information relating to the

Class ETF Shares, and to ensure fair and orderly markets for Class ETF Shares.

(2) Other Related Proposed Rule Changes

The Exchange also proposes changes to accommodate Class ETF Shares in other Exchange rules. The Exchange proposes to add Class ETF Shares to the definition of UTP Security in BZX Rule 1.5(ee) and to amend BZX Rule 14.11(c)(3)(A)(i)(a) to include Class ETF Shares in the definition of "Derivative Securities Products." In addition, the Exchange proposes to amend BZX Rule 14.10(e)(1)(E)(ii) to exempt Class ETF Shares from the requirements of BZX Rule 14.10(i)(1) in connection with the acquisition of the stock or assets of an affiliated registered investment company in a transaction that complies with Rule 17a–8 under the Investment Company Act and does not otherwise require shareholder approval under the Investment Company Act and the rules thereunder or any other Exchange rule.⁶⁰ The Exchange also proposes to amend BZX Rule 14.10(e)(1)(F)(ii) to include Class ETF Shares in the definition of "Derivative Securities," which, for purposes of BZX Rule 14.10, would exempt Class ETF Shares from the requirements relating to Independent Directors (as set forth in BZX Rule 14.10(c)(2)), Compensation Committees (as set forth in BZX Rule 14.10(c)(4)), Director Nominations (as set forth in BZX Rule 14.10(c)(5)), Code of Conduct (as set forth in BZX Rule 14.10(d)), and Meetings of Shareholders (as set forth in BZX Rule 14.10(f)). In addition, these issuers would be exempt from the requirements relating to Audit Committees (as set forth in BZX Rule 14.10(c)(3)), except for the applicable requirements of Rule 10A–3 under the Act.⁶¹ These proposed changes incorporate proposed BZX Rule 14.11(n) into the existing framework of BZX's rules, and therefore the Commission finds that such changes are consistent with Section 6(b)(5) of the Act.

B. Consistency With Section 6(b)(1) of the Act

The Commission also finds that the proposed rule change, as modified by

⁵⁴ See *supra* note 27 and accompanying text. See also BZX Rule 14.11(a) (requiring, among other things, that "[a] Company with securities listed under this Rule 14.11 must provide the Exchange with prompt notification after the Company becomes aware of any noncompliance by the Company with the requirements of Rule 14.11.").

⁵⁵ 15 U.S.C. 78f(b)(5).

⁵⁶ The Exchange will obtain a representation from the issuer of Class ETF Shares that the net asset value per share will be calculated daily and made available to all market participants at the same time, and the requirements pertaining to the Multi-Class Fund Exemptive Relief and Rule 6c–11 under the Investment Company Act in proposed Rule 14.11(n) will be satisfied. See *supra* note 29 and accompanying text.

⁵⁷ See *id.*

⁵⁸ See *supra* note 26 and accompanying text.

⁵⁹ See *supra* note 40 and accompanying text.

⁶⁰ The Exchange states that these proposed changes would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange. See *supra* note 28 and accompanying text.

⁶¹ See 17 CFR 240.10A–3 (Listing standards relating to audit committees). The Exchange represents that the issuer of Class ETF Shares will be required to comply with Rule 10A–3 under the Act for the initial and continued listing of Class ETF Shares, as provided under BZX Rule 14.10(e)(1)(E). See *supra* notes 21 and 28 and respective accompanying text.

Amendment No. 2, is consistent with Section 6(b)(1) of the Act,⁶² which requires, among other things, that the Exchange is so organized and has the capacity to be able to enforce compliance by its members and persons associated with its members with the rules of the Exchange. The Exchange represents that, consistent with Section 6(b)(1) of the Act,⁶³ it has the capacity to enforce proposed BZX Rule 14.11(n) and that it will: (1) monitor for compliance to ensure that the Multi-Class Fund is and continues to be eligible to operate an ETF Class as an ETF pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (2) monitor for compliance to ensure that the ETF Class is and continues to be in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (3) monitor for compliance to ensure that the ETF Class and the Multi-Class Fund each satisfies the requirements of proposed BZX Rule 14.11(n), as applicable, on an initial and continued listing basis; (4) review the website of the Class ETF Shares to ensure that the requirements of Rule 6c–11 under the Investment Company Act are being met; and (5) obtain a representation from the issuer of the Class ETF Shares that the requirements of Rule 6c–11 under the Investment Company Act and of the Multi-Class Fund Exemptive Relief will be continuously satisfied, and that the issuer will notify the Exchange of any failure to do so. The Exchange also represents that it will comply with all the requirements of Rule 19b–4(e) to specifically note that such Class ETF Shares are being listed on the Exchange pursuant to Rule 14.11(n).⁶⁴

The Exchange states that it will employ numerous intraday alerts to notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain

disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. The Exchange also states that BZX Rule 14.11(a) requires any issuer to provide the Exchange with prompt notification after it becomes aware of any non-compliance with proposed BZX Rule 14.11(n),⁶⁵ which would include any failure of the issuer to comply with Rule 6c–11 under the Investment Company Act or with the terms and conditions of the Multi-Class Fund Exemptive Relief.⁶⁶ Further, proposed BZX Rule 14.11(n)(4)(B)(i)(c) requires that the Exchange commence delisting proceedings for Class ETF Shares if, following the initial 12-month period after commencement of trading on the Exchange, there are fewer than 50 beneficial holders of the Class ETF Shares for 30 or more consecutive trading days.⁶⁷ Finally, the Exchange deems Class ETF Shares to be equity securities and represents, therefore, that such Class ETF Shares would be subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.⁶⁸ The Exchange states that Class ETF Shares will be subject to rules governing Exchange member disclosure obligations in connection with equities trading, and that Rule 6c–11 under the Investment Company Act does not change the applicability of these Exchange rules with respect to these securities.⁶⁹

This approval order is based on all of the Exchange's representations and descriptions in the proposed rule change, including those set forth above and in Amendment No. 2, which the Commission has carefully evaluated as

discussed above. For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Sections 6(b)(1) and 6(b)(5) of the Act⁷⁰ and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendment No. 2 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether the proposed rule change, as modified by Amendment No. 2, 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–ChoeBZX–2025–076 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–ChoeBZX–2025–076. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ChoeBZX–2025–076 and should be submitted on or before December 19, 2025.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 2

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 2, prior to the 30th day after the date of publication of Amendment No. 2 in the **Federal Register**. Amendment No. 2

⁷⁰ 15 U.S.C. 78f(b)(1) and 15 U.S.C. 78f(b)(5), respectively.

⁶² 15 U.S.C. 78f(b)(1).

⁶³ *Id.*

⁶⁴ Rule 19b–4(e) requires an SRO seeking to rely on Rule 19b–4(e) to post on its publicly available internet website within five business days after commencement of trading a new derivative securities product the following information relating to the new derivative securities product, using the most recent versions of the XML schema and the associated PDF renderer as published on the Commission's website: (A) type of issuer; (B) class; (C) name of underlying instrument; (D) if the underlying instrument is an index, whether it is broad-based or narrow-based; (E) ticker symbol(s); (F) market(s) upon which securities composing the underlying instrument trade; (G) settlement methodology; and (H) position limits (if applicable). See 17 CFR 240.19b–4(e)(2)(ii). See also *supra* note 18 and accompanying text.

⁶⁵ See BZX Rule 14.11(a) (requiring a company with securities listed under BZX Rule 14.11 to provide the Exchange with prompt notification after the company becomes aware of any non-compliance by the company with the requirements of Rule 14.11).

⁶⁶ The Exchange further represents that failure by an issuer to notify the Exchange of non-compliance pursuant to Rule 14.11(a) would itself be considered non-compliance with the requirements of BZX Rule 14.11 and would subject the Class ETF Shares to potential trading halts and the delisting process under BZX Rule 14.12. See *supra* note 27 and accompanying text.

⁶⁷ See proposed BZX Rule 14.11(n)(4)(B)(i)(c).

⁶⁸ See *supra* note 30 and accompanying text.

⁶⁹ With respect to trading in Class ETF Shares, the Exchange further represents that all of the BZX member obligations relating to product description and prospectus delivery requirements will continue to apply in accordance with the Exchange rules and federal securities laws, and BZX will continue to monitor its members for compliance with such requirements, which are not changing as a result of the Multi-Class Fund Exemptive Relief order issued under the Investment Company Act. See *supra* note 30 and accompanying text.

reflects the Commission's grant of the Multi-Class Fund Exemptive Relief and provides additional clarity with respect to the application of the Exchange's proposed listing standards and the requirements of the Multi-Class Fund Exemptive Relief. Amendment No. 2 also makes certain additional corrections that are minor and technical in nature. In addition, the proposal, as modified by Amendment No. 1, has been subject to public comment and no comments have been received.

The Commission finds that Amendment No. 2 to the proposed rule change raises no novel regulatory issues that have not previously been subject to comment, and is reasonably designed, among other things, to prevent fraudulent and manipulative acts and practices, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest. The Commission also finds that Amendment No. 2 to the proposed rule change is consistent with Section 11A(a)(1)(C)(iii) of the Act.⁷¹ Accordingly, pursuant to Section 19(b)(2) of the Act,⁷² the Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁷³ that the proposed rule change (SR-CboeBZX-2025-076), as modified by Amendment No. 2, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21400 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0067]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Form S-11—Registration Statement

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form S-11 (17 CFR 239.18) is the registration statement form used to register securities issued by real estate investment trusts or by issuers whose business is primarily that of acquiring and holding for investment interests in real estate under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*). The information collected is intended to ensure the adequacy of information available to investors in connection with securities offerings. The information required by Form S-11 is mandatory, and Form S-11 is publicly available on the Commission's Electronic Data Gathering, Analysis, and Retrieval ("EDGAR") system. We estimate that Form S-11 takes approximately 732.48 hours per response and is filed once per year by approximately 14 issuers, for a total of approximately 14 responses annually. We estimate that 25% of the 732.48 hours per response is carried internally by the issuer for annual reporting burden of 2,564 hours ((25% × 732.48 hours per response) × 14 responses). We estimate that 75% of the 732.48 hours per response is carried externally by outside professionals retained by the issuer at an estimated rate of \$600 per hour for a total annual cost burden of \$4,614,624 ((75% × 732.48 hours per response) × \$600 per hour × 14 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202508-3235-005 or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by December 29, 2025.

Dated: November 24, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21388 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104245; File No. SR-CBOE-2025-081]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 5.34 To Adopt a Wide Market Protection Mechanism

November 24, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 19, 2025, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 5.34 to adopt a wide market protection mechanism designed to reduce the risk of orders executing at extreme or adverse prices when the national best bid and offer ("NBBO") is determined to be wide. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>), the Exchange's website (https://www.cboe.com/us/options/regulation/rule_filings/bzx/), and 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 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.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁷¹ See *supra* note 40 and accompanying text.

⁷² 15 U.S.C. 78s(b)(2).

⁷³ *Id.*

⁷⁴ 17 CFR 200.30-3(a)(12).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this rule filing is to amend Rule 5.34(a), Order and Quote Price Protection Mechanisms and Risk Controls (Simple Orders), to adopt a wide market protection mechanism designed to reduce the risk of orders executing at extreme or adverse prices when the NBBO is determined to be wide.³ The proposed wide market protection mechanism will leverage the existing iterative drill-through protection mechanism for certain orders when the NBBO is wide and will initiate a drill-through pause on applicable inbound market or limit orders or elected Stop (Stop-Loss)⁴ or Stop-Limit⁵ orders which would either execute or post to the Book⁶ at potentially extreme prices.

Drill-through price protection is currently described in Exchange Rule 5.34(a)(4). Under Rule 5.34(a)(4)(A), if a buy (sell) order enters the Book at the

conclusion of the opening auction process or would execute or post to the Book when it enters the Book, the System⁷ executes the order up (down) to a buffer amount (the Exchange determines the buffer amount on a class and premium basis) above (below) the offer (bid) limit of the Opening Collar⁸ or the National Best Offer ("NBO") (National Best Bid ("NBB")) that existed at the time of order entry, respectively (the "drill-through price").⁹

Rule 5.34(a)(4)(C) establishes an iterative drill-through process, whereby orders will rest in the Book for multiple time periods and at more aggressive displayed prices during each time period.¹⁰ Specifically, for a market order with a Time-in-Force of Day or a limit order (or unexecuted portion) with a Time-in-Force of Day, Good-til-Cancelled ("GTC"), or Good-til-Date ("GTD"), the System enters the order in the Book with a displayed price equal to the drill-through price. The order (or unexecuted portion) will rest in the Book at the drill-through price for the duration of consecutive time periods (the Exchange determines on a class-by-class basis the length of the time period in milliseconds, which may not exceed three seconds) (each time period is referred to as an "iteration").¹¹ Following the end of each period, the System adds (if a buy order) or subtracts (if a sell order) one buffer amount (the Exchange determines the buffer amount on a class-by-class basis) to the drill-through price displayed during the immediately preceding period (each new price becomes the "drill-through price").¹² The order (or unexecuted portion) rests in the Book at that new drill-through price for the duration of the subsequent period. The System applies a timestamp to the order (or unexecuted portion) based on the time it enters or is re-priced in the Book for priority reasons. The order continues through this iterative process until the earliest of the following to occur: (a) the

order fully executes; (b) the User¹³ cancels the order; or (c) the buy (sell) order's limit price equals or is less (greater) than the drill-through price at any time during application of the drill-through mechanism, in which case the order rests in the Book at its limit price, subject to a User's instructions.

Currently, there are common scenarios in which certain orders are trading at prices that are, for reasons described below, artificially wide. For example, certain trading strategies result in a significant number of simple Stop (Stop-Loss) and Stop-Limit orders resting in the Book and then being triggered simultaneously by a common event. The receipt of large quantities of market and limit orders on the same side of a series results in rapid removal of liquidity without opportunity for replenishment (and potential related triggers of risk protections). This results in potentially extreme or adverse execution prices as risk is re-evaluated by Market-Makers and quotes are replenished, typically within seconds of the start of the triggering event. Additionally, the Exchange has observed an increase in resting Stop (Stop-Loss) or Stop-Limit orders that are simultaneously triggered around the opening of the relevant trading session and trading at extremely wide price levels, up to Obvious Error prices. Similarly, Stop (Stop-Loss) and Stop-Limit orders may be triggered on a trade (rather than an NBBO update) that exhausts liquidity, causing the triggered order(s) to execute at the next available bid/offer, which may be at an extreme level, rather than affording the order the benefit of drill-through price protection by displaying the order at the price of the triggering trade and iterating from there.

The Exchange now proposes rule changes designed to prevent trades at extreme or adverse price levels in such scenarios, when quotes are wide or when orders are removing liquidity in rapid succession. The Exchange proposes to amend Rule 5.34 to add a wide market protection mechanism that will leverage the existing iterative drill-through protection mechanism for certain orders when the NBBO is considered "wide" and will initiate a drill-through pause on applicable near-marketable inbound market or limit orders or elected Stop (Stop-Loss) or Stop-Limit orders which would either execute or post to the Book at potentially extreme or adverse prices.

³ The Exchange notes it currently has a Market Order NBBO Width Protection Mechanism set forth in Rule 5.34(a)(2); the proposed rule change does not result in changes to the Market Order NBBO Width Protection Mechanism, which is infrequently triggered. In general, the current Market Order NBBO Width Protection Mechanism applies when the NBBO is significantly wider than will be considered under the proposed wide market protection mechanism. Further, the Market Order NBBO Width Protection is applicable only to market orders and does not apply to Stop (Stop-Loss) orders. The proposed wide market protection mechanism is applicable to market and limit orders (subject to certain exceptions), and is intended to "catch" more orders. Unlike the Market Order NBBO Width Protection Mechanism, which cancels orders too far outside the NBBO, the proposed mechanism will trigger the drill-through process for applicable orders and thus provide additional execution opportunities.

⁴ A "Stop (Stop-Loss)" order is an order to buy (sell) that becomes a market order when the consolidated last sale price (excluding prices from complex order trades if outside of the NBBO) or NBB (NBO) for a particular option contract is equal to or above (below) the stop price specified by the User. Users may not designate a Stop Order as All Sessions. Users may not designate bulk messages as Stop Orders. A User may not designate a Stop order as Direct to PAR. See Rule 5.6(c) (definition of "Stop (Stop-Loss)" order).

⁵ A "Stop-Limit" order is an order to buy (sell) that becomes a limit order when the consolidated last sale price (excluding prices from complex order trades if outside the NBBO) or NBB (NBO) for a particular option contract is equal to or above (below) the stop price specified by the User. A User may not designate a Stop-Limit Order as All Sessions or RTH and Curb. Users may not designate bulk messages as Stop-Limit Orders. A User may not designate a Stop-Limit order as Direct to PAR. See Rule 5.6(c) (definition of "Stop-Limit" order).

⁶ "Book" means the electronic book of simple orders and quotes maintained by the System, which single book is used during both the regular trading hours and global trading hours trading sessions. See Rule 1.1 (definition of, "Book").

⁷ "System" means the Exchange's hybrid trading platform that integrates electronic and open outcry trading of option contracts on the Exchange and includes any connectivity to the foregoing trading platform that is administered by or on behalf of the Exchange, such as a communications hub. See Rule 1.1 (definition of, "System").

⁸ See Rule 5.31(a) for the definition of Opening Collars.

⁹ See Rule 5.34(a)(4)(A).

¹⁰ The Exchange will announce to Trading Permit Holders the buffer amount and the length of the time periods in accordance with Rule 1.5. The Exchange notes that each time period will be the same length (as designated by the Exchange), and the buffer amount applied for each time period will be the same.

¹¹ See Rule 5.34(a)(4)(C).

¹² See Rule 5.34(a)(4)(C).

¹³ The term "User" shall mean any Trading Permit Holder or Sponsored User who is authorized to obtain access to the System pursuant to Rule 5.5.

Specifically, the Exchange proposes to add new Rule 5.34(a)(5) to establish a wide market protection mechanism. Under proposed Rule 5.34(a)(5)(A), if (i) when the NBBO is “wide,” the System receives a buy (sell) order with a price that is more than a buffer amount above (below) the NBB (NBO) or (ii) a Stop (Stop-Loss) or Stop-Limit buy (sell) order is triggered and is priced more than a buffer amount above (below) the NBB (NBO) and the NBBO after the triggering event is “wide,” the order enters the Book and is displayed at the Benchmark Price for an Exchange determined-amount of time (this time period will be considered the first drill-through iteration pursuant to Rule 5.34(a)(4)). If the order does not execute or there is any remaining size of the order following a partial execution, the order will continue the drill-through process pursuant to Rule 5.34(a)(4).

As set forth in proposed Rule 5.34(a)(5)(A), for purposes of the proposed subparagraph (5), the NBBO is “wide” if there is no NBO or the width of the NBBO for the series is equal to or greater than an amount the Exchange determines on a class-by-class basis and which is applied based on the NBB. Further, for a buy (sell) order, the Benchmark Price is the least aggressive price of (1) the NBB (NBO) plus (minus) a buffer amount determined by the Exchange on a class and premium basis;¹⁴ (2) the last trade price, if greater (less) than or equal to the NBB (NBO);¹⁵ or (3) the midpoint of the then-current NBBO. Consider the below examples.

Example #1, Demonstrating Eligibility of a Stop-Limit Order for Wide Market Protection

In this example, a buy Stop-Limit order is triggered, the NBBO after the triggering event is determined to be wide, and the limit price is more than a buffer amount above the NBB. Under the proposed rules, the order will be paused at the Benchmark Price and begin drill-through iteration. Assume for purposes of this example, the market will be considered wide pursuant to proposed Rule 5.34(a)(5)(A)(i) if the width of the NBBO for the series is equal to or greater than \$1.50. Further assume for this example, the buffer amount to determine limit order

eligibility based on price is 80% of the width of NBBO.

Order 1: Stop-Limit Buy 5 contracts @ 3.33, Stop Price = \$2.30
MM1 Quote: 5 @1.95 x 5 @3.65
MM2 Quote: 5 @1.95 x 5 @2.30 (NBBO, not wide)

Order 2: Buy 5 @2.30
Order 2 trades with MM2 Quote at 2.30; as a result, Order 1 is elected.

The resulting NBBO after the triggering event is 1.95 x 3.65 (*i.e.*, NBBO width equal to \$1.70), which is considered wide, and Order 1 is triggered with a limit price of \$3.33, which is greater than the Exchange-determined buffer amount above the NBB (*i.e.*, NBB of 1.95 + (NBBO width of 1.70 x 0.80 buffer) = 3.31). Thus, Order 1 is subject to the wide market protection mechanism.

Example #2, Demonstrating Determination of Benchmark Price

In this example, a buy Stop (Stop-Loss) order is triggered by a quote, the NBBO after the triggering event is determined to be wide, and the price is more than a buffer amount above the NBB. Under the proposed rules, the order will be paused at the Benchmark Price and begin drill-through iteration. Assume for purposes of this example, the market will be considered wide pursuant to proposed Rule 5.34(a)(5)(A)(i) if the width of the NBBO for the series is equal to or greater than \$1.50. Further assume for this example, the buffer amount to determine the order eligibility based on price is 80% of the width of NBBO and the buffer amount used in determining Benchmark Price is 0.75.

Order 1: Stop (Stop-Loss) Buy 5 @3.40, Stop Price = \$2.00
MM1 Quote: 5 @1.95 x 5 @3.75
MM2 Quote 5 @1.95 x 5 @2.30 (NBBO, not wide)

Order 2: Buy 5 @2.30
Order 2 trades with MM2 Quote at 2.30; as a result, Order 1 is elected.

The resulting NBBO after the triggering event is 1.95 x 3.75 (*i.e.*, NBBO width equal to \$1.80), which is considered wide, and Order 1 is triggered with a price of \$3.40, which is greater than the Exchange-determined buffer amount above the NBB (*i.e.*, NBB of 1.95 + (NBBO width of 1.80 x 0.80 buffer) = 3.39). Thus, Order 1 is subject to the wide market protection mechanism. The Benchmark Price is 2.30, determined as the least aggressive of:

- The NBB (1.95) plus a buffer amount determined by the Exchange on a class and premium basis (0.75): 2.70
- Last Trade Price: 2.30

- The midpoint of the then-current NBBO: 2.85

Thus, executions of Order 1 up to \$2.30 will be considered the initial drill-through iteration, as the order becomes subject to the drill-through price protection mechanism under Rule 5.34(a)(4)(C).

The Exchange proposes to add Rule 5.34(a)(5)(B) to specify that the wide market protection mechanism applies during all trading sessions, except for a pre-determined amount of time prior to the close of the Regular Trading Hours (“RTH”)¹⁶ and Curb¹⁷ trading sessions (such time will be determined by the Exchange).¹⁸ This provides a final opportunity for market participants to utilize Stop (Stop-Loss) and Stop-Limit orders to exit positions if desired at the end of the trading session, in order to avoid unintended overnight risk.¹⁹

The Exchange proposes to add Rule 5.34(a)(5)(C), which states that if an order would initiate the wide market protection while the drill-through process in the applicable series is in progress pursuant to Rule 5.34(a)(4), then the System does not initiate the wide market protection and instead the order would join the ongoing drill-through as set forth in Rule 5.34(a)(4)(C)(iv). The Exchange also proposes to add Rule 5.34(a)(5)(D) to exclude bulk messages, Intermarket Sweep Orders (“ISOs”), Immediate-or-Cancel orders (“IOCs”), and M and N capacity²⁰ orders with a Time-in-Force of Day²¹ from the wide market protection mechanism; and to note that the Exchange may apply the wide market protection on a class-by-class basis.

¹⁶ RTH for transactions in equity options (including options on individual stocks, ETFs, ETNs, and other securities) are the normal business days and hours set forth in the rules of the primary market currently trading the securities underlying the options, except for options on ETFs, ETNs, Index Portfolio Shares, Index Portfolio Receipts, and Trust Issued Receipts the Exchange designates to remain open for trading beyond 4:00 p.m. Eastern Time (ET) but in no case later than 4:15 p.m. ET. RTH for transactions in index options are from 9:30 a.m. to 4:15 p.m. ET, subject to certain exceptions.

¹⁷ The Curb session begins at 4:15 p.m. and goes until 5:00 p.m. on Monday through Friday.

¹⁸ During this time, the drill-through process will not be initiated by the wide market protection mechanism, but may still apply pursuant to Rule 5.34(a)(4).

¹⁹ The Exchange notes that Rule 6.5(c), Obvious Errors, will continue to apply as it does today; there are no changes to the Obvious Error rules as a result of the proposed rule change.

²⁰ See Rule 1.1 (definition of “Capacity”).

²¹ The Exchange notes that while M and N capacity orders with a Time-in-Force of Day are excluded from the wide market protection mechanism, they may separately be subject to the drill-through price protection mechanism, as applicable.

¹⁴ In a no-bid scenario for buy orders, the NBB will be considered as zero and the Benchmark Price will be calculated accordingly. In a no-offer scenario for sell orders, the NBO will not be used; the Benchmark Price will use the less aggressive of the last trade price or the NBB plus the buffer amount determined by the Exchange on a class-by-class basis.

¹⁵ If last trade price is worse than the NBO (NBB) it will not be used as a possible Benchmark Price.

The Exchange also proposes to amend Rule 5.34(a)(1)(A)(ii)²² to exclude from the current protections for market orders in no-bid series certain orders that would be otherwise subject to wide market protection under the proposed rule changes. Currently, under Rule 5.34(a)(1)(A)(ii), if the System receives a sell market order in a series after it is open for trading with an NBB of zero, and the NBO in the series is greater than \$0.50, the System cancels or rejects the market order, or routes the market order to PAR for manual handling, subject to a User's instruction, except if a drill-through process (described in subparagraph (a)(4)) is in progress for sell orders in the series and the sell market order would be subject to the drill-through protection, then the order joins the ongoing drill-through process in the then-current iteration and at the then-current drill-through price, regardless of NBBO. The Exchange proposes to amend Rule 5.34(a)(1)(A)(ii) to note that in the event the System receives a sell market order in a series after it is open for trading with an NBB of zero and the NBO in the series is greater than \$0.50, if the order is subject to wide market protection pursuant to proposed subparagraph (a)(5), then the order enters the Book and is displayed at the Benchmark Price for an Exchange determined-amount of time (this time period will be considered the first drill-through iteration pursuant to subparagraph (a)(4)), with any remaining size continuing the drill-through process pursuant to subparagraph (a)(4).

Finally, the Exchange proposes to amend Rule 5.34(a)(1)(B) to exclude from the current protections for market orders in no-offer series certain orders that would be otherwise subject to wide market protection under the proposed rule changes or drill-through protections pursuant to current Rule 5.34(a)(4). Currently under Rule 5.34(a)(1)(B), if the System receives a buy market order in a series after it is open for trading with an NBO of zero, the System cancels or rejects the market order. The Exchange proposes to amend Rule 5.34(a)(1)(B) to note that in the event the System receives a buy market order in a series after it is open for trading with an NBO of zero, if the order is subject to wide market protection pursuant to proposed subparagraph (a)(5), then the order enters the Book and is displayed at the Benchmark Price for an Exchange determined-amount of time (this time period will be considered the first drill-

through iteration pursuant to subparagraph (a)(4)), with any remaining size continuing the drill-through process pursuant to subparagraph (a)(4); or if a drill-through process (described in current subparagraph (a)(4)) is in progress for buy orders in the series and the buy market order would be subject to the drill-through protection, then the order joins the ongoing drill-through process in the then-current iteration and at the then-current drill-through price, regardless of NBBO.

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.²³ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²⁴ requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²⁵ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change to implement a wide market protection mechanism will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors, because it will provide applicable orders with additional and consistent execution opportunities and price protections. As noted above, the wide market protection mechanism is effectively an extension of the Exchange's current drill-through price protection, of which the primary purpose is to prevent orders from executing at prices "too far away" from the market when they enter the Book for potential execution. The Exchange believes the proposed rule change is

consistent with this purpose, because Users who submit applicable orders or have orders triggered in markets that are wider than expected, possibly due to wide quotes or orders removing liquidity in rapid succession, will receive price protection against execution at potentially extreme or adverse prices and additional execution opportunities.

Further, the proposed rule change to leverage the existing iterative drill-through protection mechanism for certain orders when the NBBO is considered "wide" allows these orders to receive the same level of price protection as other orders otherwise subject to the drill-through process. The proposed rule change will allow orders in wide markets additional execution opportunities while continuing to protect them against execution at potentially extreme prices, by providing the opportunity for execution at reasonable prices by allowing for liquidity replenishment that may result in more aggressive prices, especially during times when liquidity may require additional time to replenish, such as near the beginning of a trading session.

The Exchange believes the proposal will enhance risk protections, the individual firm benefits of which flow downstream to counterparties both at the Exchange and at other options exchanges, which increases systemic protections as well. The Exchange believes enhancing risk protections will allow Users to enter orders, including Stop (Stop-Loss) and Stop-Limit orders, and quotes with further reduced fear of inadvertent exposure to excessive risk, which will benefit investors through increased exposure to liquidity for the execution of their orders.

The Exchange also believes the proposed changes regarding the application of the wide market protection mechanism during Exchange trading sessions will protect investors, as the proposed application allows market participants a final opportunity to utilize Stop (Stop-Loss) and Stop-Limit orders to exit positions if desired at the end of the relevant trading session, in order to avoid unintended overnight risk. Further, the proposed changes add transparency to the rules regarding the wide market protection functionality and provide greater certainty as to the application of the process.

Additionally, the Exchange believes changes to specifically exclude bulk messages, ISOs, and IOCs from the wide market protection mechanism (similar to the drill-through price protection mechanism) is reasonable and

²² The Exchange also proposes a non-substantive change to correct a typographical error within Rule 5.34(a)(1)(A)(ii), to change "expect" to "except."

²³ 15 U.S.C. 78f(b).

²⁴ 15 U.S.C. 78f(b)(5).

²⁵ *Id.*

appropriate, given the iterative pricing process would be inconsistent with the orders instruction (and thus the user's intent). Further, the Exchange believes the proposed change to exclude M and N capacity orders with a Time-in-Force of Day from the wide market protection is reasonable, as Market-Makers are positioned to observe and subsequently address wide market scenarios, by tightening the NBBO with an order or quote.

The Exchange also believes the proposed change to clarify that the System will not initiate the wide market protection while a drill-through process in the applicable series is in progress is reasonable, as it will bring transparency and clarity to the rulebook regarding how the wide market protection mechanism interacts with the drill-through price protection mechanism, to the benefit of investors. This proposed change is consistent with current drill-through functionality, where incoming orders that enter the Book while the drill-through is in progress and that would be subject to the drill-through protection join the on-going drill-through process.²⁶

Additionally, the Exchange believes changes to specifically exclude from the current protections for market orders in no-bid (offer) series certain orders that would otherwise be subject to wide market protection will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors. Specifically, the Exchange believes the change to exclude from the current protections for market orders in no-bid (offer) series certain orders that would otherwise be subject to wide market protection may allow opportunity for execution than if they were immediately canceled or rejected. This proposed rule change may increase execution opportunities for Users that submit sell market orders with an NBB of zero when the NBO in the series is greater than \$0.50 (in the case of market orders in no-bid series protections) or buy market orders with an NBO of zero while still providing protection against executions at potentially erroneous prices. Similarly, the Exchange believes the change to allow buy market orders received by the System when the NBO is zero to be subject to the drill-through process is reasonable, as it may allow opportunity for execution of such orders, rather than if they were immediately canceled or rejected. This change aligns market order in no-bid (offer) series protection for Users that submit sell market orders

with an NBB of zero when the NBO in the series is greater than \$0.50 (in the case of market orders in no-bid series protections) with how the Exchange will handle buy market orders with an NBO of zero.

Finally, the Exchange believes the proposed change to apply the wide market protection on a class-by-class basis is reasonable, as classes may have different trading characteristics or may be affected differently by market conditions. The proposal will provide the Exchange with flexibility to apply wide market protections in a manner which accounts for material differences across option classes, thereby enhancing investor protection while minimizing unnecessary market disruption. Further, the Exchange believes the proposed changes are not unfairly discriminatory, as wide market protection applies uniformly to all market participants within each class. This approach is consistent with the Exchange's existing practice of applying certain other order and quote price protection and risk controls, such as the limit order fat finger check for simple orders,²⁷ on a class-by-class basis where product characteristics warrant differential treatment in regard to risk protections.

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. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the wide market protection functionality will apply to all applicable orders in a class in the same manner. Additionally, it will provide the same price protection and execution opportunities to relevant orders that are currently provided to orders that are subject to the drill-through price protection process, as the wide market protection mechanism is effectively an extension of the Exchange's current drill-through price protection. As noted above, the Exchange believes it is not unfairly discriminatory to apply this protection on a class-by-class basis, as wide market protection applies uniformly to all market participants within each class. This approach is consistent with the Exchange's existing practice of applying certain other order and quote price protection and risk controls, such as the limit order fat

finger check for simple orders,²⁸ on a class-by-class basis where product characteristics warrant differential treatment in regard to risk protections.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as the proposed rule change relates specifically to price protections offered on the Exchange and how the System handles orders as part of these price protection mechanisms. The proposed wide market protection mechanism expands the current drill-through price protection mechanism and provides relevant orders with improved protection against execution at potentially extreme or adverse prices through drill-through price protection.

The Exchange believes the proposed rule change would ultimately provide all market participants with additional execution opportunities when appropriate while providing protection from extreme or adverse execution. The Exchange believes the proposal will enhance risk protections, the individual firm benefits of which flow downstream to counterparties both at the Exchange and at other options exchanges, which increases systemic protections as well. The Exchange believes enhancing risk protections will allow Users to enter orders, including Stop (Stop-Loss) and Stop-Limit orders, and quotes with further reduced fear of inadvertent exposure to excessive risk, which will benefit investors through increased exposure to liquidity for the execution of their orders. Without adequate risk management tools, Trading Permit Holders could reduce the amount of order flow and liquidity they provide. Such actions may undermine the quality of the markets available to customers and other market participants. Accordingly, the proposed rule change is designed to encourage Trading Permit Holders to submit additional order flow and liquidity to the Exchange. The proposed change may similarly provide additional execution opportunities, which further benefits liquidity, especially during times when liquidity may require additional time to replenish, such as near the beginning of a trading session.

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.

²⁶ See Rule 5.34(a)(4)(iv).

²⁷ See Rule 5.34(c)(1)(A).

²⁸ See Rule 5.34(c)(1)(A).

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) of the Act²⁹ and Rule 19b-4(f)(6)³⁰ thereunder. Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act³¹ and Rule 19b-4(f)(6)³² thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)³³ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),³⁴ 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 proposed rule change may become operative immediately upon filing. The Exchange believes waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to more expeditiously implement the proposed changes which will provide applicable orders with improved protection against execution at potentially extreme or adverse prices via the wide market protection mechanism. For these reasons, and because the proposed rule change does not raise any novel legal or regulatory issues, the Commission finds that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.³⁵

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-CBOE-2025-081 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-CBOE-2025-081. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CBOE-2025-081 and should be submitted on or before December 19, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-21404 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0066]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Form S-8-Securities Act Registration Statement

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form S-8 (17 CFR 239.16b) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) is the primary registration statement used by eligible registrants to register securities to be issued in connection with an employee benefit plan. The information collected is intended to ensure the adequacy of information available to investors in connection with securities offerings. The information required by Form S-8 is mandatory, and Form S-8 is publicly available on the Commission's Electronic Data Gathering, Analysis, and Retrieval ("EDGAR") system. We estimate that Form S-8 takes approximately 28.25 hours per response to prepare and is filed once per year by approximately 2,541 respondents. We estimate that 50% of the burden (14.125 hours) is carried internally by the issuer for a total annual reporting burden of 35,892 (14.125 hours per response × 2,541 responses). We estimate that 50% of the burden is carried externally by outside professionals at a rate of \$600 per hour for a total cost burden of \$21,534,975 (14.125 hours per response × \$600 per hour × 2,541 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

²⁹ 15 U.S.C. 78s(b)(3)(A).

³⁰ 17 CFR 240.19b-4(f)(6).

³¹ 15 U.S.C. 78s(b)(3)(A).

³² 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³³ 17 CFR 240.19b-4(f)(6).

³⁴ 17 CFR 240.19b-4(f)(6)(iii).

³⁵ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on

efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

³⁶ 17 CFR 200.30-3(a)(12), (59).

The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202508-3235-004 or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by December 29, 2025.

Dated: November 25, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21494 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104248; File No. SR-DTC-2025-016]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the DTC Rules To Align With Exchange Act Rule 17ad-26

November 24, 2025.

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 November 21, 2025, The Depository Trust Company (“DTC”) 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 clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(4) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of certain changes to Rule 32(A) (Wind-down of the Corporation) of the Rules of The Depository Trust Company (“DTC”)⁵ to revise certain defined terms and make related technical changes to align with Exchange Act Rule 17ad-26⁶

(“SEC Rule 17ad-26” or “Rule 17ad-26”) promulgated by the Commission.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission promulgated Rule 17ad-26,⁷ which requires that plans for the recovery and orderly wind-down of a covered clearing agency, such as DTC, include certain specific elements. The Commission recently approved DTC’s proposed rule change to reflect the requirements of Rule 17ad-26 in the DTC Recovery & Wind-down Plan (the “Plan” or “RWP”).⁸ For purposes of implementing certain aspects of the RWP, DTC is proposing to revise certain defined terms and make certain technical changes to DTC Rule 32(A) (Wind-down of the Corporation),⁹ in order to align with how they are referred to in the Plan and to conform with the definitions set forth in Rule 17ad-26.¹⁰

A. Proposal To Modify or Add Certain Defined Terms in DTC Rule 32(A) (Wind-Down of the Corporation)

(i) Proposal To Replace the Term “Critical Services” With “Core Services”

Consistent with SEC Rule 17ad-26(a)(1),¹¹ DTC is proposing to modify

⁷ *Id.*

⁸ See Securities Exchange Act Release No. 103221 (June 10, 2025), 90 FR 25414 (June 16, 2025) (SR-DTC-2025-007).

⁹ DTC Rule 32(A) (Wind-down of the Corporation), *supra* note 5.

¹⁰ *Supra* note 6.

¹¹ *Id.* In the Adopting Release covering Rule 17ad-26, it was noted that “The Commission is modifying the final rule to refer to “core payment, clearance, and settlement services” rather than “critical payment, clearance, and settlement services” (hereinafter, referred to as “core services”) to improve clarity and consistency with terminology in other rules, such as Rule 17ad-25(i), 242 which concerns the governance of “service providers for core services.” Furthermore, the use of “core” as opposed to “critical” helps distinguish a CCA’s obligations under Rule 17ad-26 from those under 17 CFR 242.1000 through 242.1007

DTC Rule 32(A) to replace all references to “Critical Services” with “Core Services.” Use of the descriptive term “Core” rather than “Critical” would not affect DTC’s identification, classification or description of these services in the RWP. Similarly, the proposed rule filing would replace all references to “Non-Critical Services” with “Non-Core Services.”

(ii) Proposal To Modify the Defined Terms “Recovery Plan” and “Wind-Down Plan”

For purposes of consistency with SEC Rule 17ad-26(b),¹² DTC is proposing to capitalize references to the terms “Recovery” and “Orderly Wind-down,” and add an associated reference to the definition of these terms as set forth under SEC Rule 17ad-26(b)¹³ within the definitions of “Recovery Plan” and “Wind-down Plan” in DTC Rule 32(A).

B. Implementation of the Proposal

As noted above, the principal purpose of the proposed rule change is to revise certain defined terms and make related technical changes to DTC Rule 32(A) (Wind-down of the Corporation) to align with Rule 17ad-26.¹⁴ This would help to facilitate implementation of certain aspects of the RWP in a manner consistent with SEC Rule 17ad-26 and the amended RWP recently approved by the Commission.¹⁵ Based on the compliance date of SEC Rule 17ad-26 that was established by the Commission,

(“Regulation SCI”), which addresses, in the context of clearing agencies subject to the rule, “critical systems” that support clearance and settlement. The Commission further noted that “Use of the descriptive term “core” rather than “critical” does not affect the Commission’s guidance stated in the RWP Proposing Release on identifying those services.”

¹² *Id.*

¹³ *Id.* Pursuant to SEC Rule 17ad-26(b), “Recovery” means the actions of a covered clearing agency, consistent with its rules, procedures, and other ex ante contractual arrangements, to address any uncovered loss, liquidity shortfall, or capital inadequacy, whether arising from participant default or other causes (such as business, operational, or other structural weaknesses), including actions to replenish any depleted prefunded financial resources and liquidity arrangements, as necessary to maintain the covered clearing agency’s viability as a going concern and to continue its provision of core services, as identified by the covered clearing agency pursuant to paragraph (a)(1) of this section. The term “Orderly wind-down” means the actions of a covered clearing agency to effect the permanent cessation, sale, or transfer of one or more of its core services, as identified by the covered clearing agency pursuant to paragraph (a)(1) of this section, in a manner that would not increase the risk of significant liquidity, credit, or operational problems spreading among financial institutions or markets and thereby threaten the stability of the U.S. financial system.”

¹⁴ *Id.*

¹⁵ *Supra* note 8.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(4).

⁵ Terms not otherwise defined herein have the meaning set forth in the DTC Rules, By-Laws and Organization Certificate (the “Rules”), available at www.dtcc.com/legal/rules-and-procedures.

⁶ Covered Clearing Agency Resilience and Recovery and Orderly Wind-down Plans, Exchange Act Release No. 101446 (Oct. 25, 2024), 89 FR 91000 (Nov. 18, 2024) (S7-10-23).

the proposed rule change would become operative on December 15, 2025.¹⁶

2. Statutory Basis

(B) Clearing Agency's Statement on Burden on Competition

DTC believes that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, DTC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,¹⁷ Rule 17ad-22(e)(3)(ii) under the Act,¹⁸ and Rule 17ad-26 under the Act¹⁹ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the DTC Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.²⁰ The proposed rule change would help to ensure that the Rules are accurate and clear to participants in the event that the RWP is ever needed to be implemented by DTC. When participants better understand their rights and obligations regarding the Rules, such participants are more likely to act in accordance with the Rules, which DTC believes would promote the prompt and accurate clearance and settlement of securities transactions. As such, DTC believes that the proposed changes would be consistent with Section 17A(b)(3)(F) of the Act.²¹ Further, by providing clarity on the Rules covering a DTC recovery and orderly wind-down, the proposed rule change would help ensure the continuity of DTC's core functions for the markets served by DTC, and thereby promote the prompt and accurate clearance and settlement of securities transactions.

Rule 17ad-22(e)(3)(ii) under the Act²² requires DTC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively

managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses. By ensuring that defined terms in the relevant Rules are consistent with how such terms are defined under Rule 17ad-26 and how they are referred to in the Plan, DTC believes that the proposed rule change is designed to support the maintenance of the and, as such, meets the requirements of Rule 17ad-22(e)(3)(ii) under the Act. Therefore, the proposed changes would help DTC to maintain the Plan in a way that continues to be consistent with the requirements of Rule 17ad-22(e)(3)(ii).²³

In addition to the requirements covering elements to be included in the recovery and wind-down plans of covered clearing agencies, SEC Rule 17ad-26 includes certain associated new defined terms.²⁴ The proposed rule change would revise certain defined terms and make related technical changes to the applicable Rules to align with SEC Rule 17ad-26. By doing so, DTC believes that the proposed rule change would help DTC maintain the Plan and the Rules in a way that is consistent with Rule 17ad-26.²⁵

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b-4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b-4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at* www.sec.gov/rules-regulations/how-submit-comment.

submit-comment. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at tradingandmarkets@sec.gov or 202-551-5777.

DTC reserves the right to not respond to any comments 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)²⁶ of the Act and paragraph (f) of Rule 19b-4 thereunder.²⁷ 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 will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-DTC-2025-016 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR-DTC-2025-016. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of DTC and on DTCC's website (<https://dtcc.com/legal/>

¹⁶ *Supra* note 6. As set forth in the Adopting Release, "[. . .] (2) the proposed rule changes and Advance Notices must be effective by December 15, 2025. These compliance dates provide sufficient time for CCAs to consider changes to their rules, policies, and procedures necessary to ensure consistency with the rules amended and adopted in this release [. . .]."

¹⁷ 15 U.S.C. 78q-1(b)(3)(F).

¹⁸ See 17 CFR 240.17ad-22(e)(3)(ii). DTC is a "covered clearing agency" as defined in Rule 17ad-22(a)(5) under the Act and must comply with paragraph (e) of Rule 17ad-22. In 2012, DTC was designated a Systemically Important Financial Market Utility by the Financial Stability Oversight Council.

¹⁹ *Supra* note 6.

²⁰ 15 U.S.C. 78q-1(b)(3)(F).

²¹ *Id.*

²² *Supra* note 18.

²³ *Id.*

²⁴ *Supra* note 6.

²⁵ *Id.*

²⁶ 15 U.S.C. 78s(b)(3)(A).

²⁷ 17 CFR 240.19b-4(f).

sec-rule-filings.aspx). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-DTC-2025-016 and should be submitted on or before December 19, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-21397 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission Investor Advisory Committee will hold a public meeting on Thursday, December 4, 2025. The meeting will begin at 10 a.m. (ET) and will be open to the public.

PLACE: The meeting will be conducted by remote means. Members of the public may watch the webcast of the meeting on the Commission's website at www.sec.gov.

STATUS: This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

PUBLIC COMMENT: The public is invited to submit written statements to the Committee. Written statements should be received on or before December 3, 2025.

Written statements may be submitted by any of the following methods:

Electronic Statements

- Use the Commission's internet submission form (<https://www.sec.gov/comments/265-28/investor-advisory-committee-meeting>); or
- Send an email message to rules-comments@sec.gov. Please include File No. 265-28 on the subject line; or

Paper Statements

- Send paper statements to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File No. 265-28. This file number should be

included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method.

The Commission will post all statements on the Commission's website. Do not include personal 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.

MATTERS TO BE CONSIDERED: The agenda for the meeting includes: welcome and opening remarks; approval of previous meeting minutes; a panel discussion regarding regulatory changes in corporate governance; a panel discussion regarding the tokenization of equity securities; a discussion of a recommendation regarding the disclosure of artificial intelligence's impact on operations; subcommittee reports; and a non-public administrative session.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

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

Dated: November 25, 2025.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2025-21546 Filed 11-25-25; 4:15 pm]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0609]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Regulation S-AM

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("SEC" or "Commission") is soliciting comments on the proposed collection of information provided for in Regulation S-AM (17 CFR part 248, subpart B), under the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*) ("FCRA"), the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), the Investment Company Act of 1940 (15 U.S.C. 80a-1 *et seq.*), and the Investment Advisers Act of 1940 (15 U.S.C. 80b-1 *et seq.*).

Regulation S-AM implements the requirements of Section 624 of the FCRA (15 U.S.C. 1681s-3) with respect to investment advisers and transfer agents registered with the Commission, as well as brokers, dealers and investment companies (collectively, "Covered Persons"). Section 624 and Regulation S-AM limit a Covered Person's use of certain consumer financial information received from an affiliate to solicit a consumer for marketing purposes, unless the consumer was given notice and a reasonable opportunity and a reasonable and simple method to opt out of such solicitations. Regulation S-AM potentially applies to all of the approximately 22,824 Covered Persons registered with the Commission, although only approximately 12,781 of them have one or more corporate affiliates, and the regulation requires only approximately 2,282 to provide consumers with an affiliate marketing notice and an opt-out opportunity.

The Commission staff estimates that there are approximately 12,781 Covered Persons having one or more affiliates, and that they each spend an average of 0.20 hours per year to review affiliate marketing practices, for, collectively, an estimated annual time burden of approximately 2,556 hours at an annual internal compliance cost of approximately \$1,686,960. The staff also estimates that approximately 2,282 Covered Persons provide notice and opt-out opportunities to consumers, and that they each spend an average of 7.6 hours per year creating notices, providing notices and opt-out opportunities, monitoring the opt-out notice process, making and updating records of opt-out elections, and addressing consumer questions and concerns about opt-out notices, for, collectively, an estimated annual time burden of approximately 17,343 hours at an annual internal compliance cost of approximately \$4,210,665. Thus, the staff estimates that the collection of information requires a total of approximately 12,781 respondents to incur an estimated total annual time burden of approximately 19,899 hours at a total annual internal cost of compliance of approximately \$5,897,625.

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will

²⁸ 17 CFR 200.30-3(a)(12).

have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by January 27, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: November 24, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21392 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0282]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reinstatement Without Change: Rule 23c-2

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("SEC" or "Commission") has submitted to the Office of Management and Budget ("OMB") a request for extension of the previously approved collection of information discussed below.

The title for the collection of information is "Rule 23c-2 (17 CFR 270.23c-2) under the Investment Company Act of 1940." Rule 23c-2(a) (17 CFR 270.23c-2(a)) under the Act provides that a closed-end fund may call or redeem any securities it has issued in accordance with the charter, provided that in instances where less than all of the outstanding shares of a class or series are called or redeemed, the call or redemption is made by lot on a pro rata basis, or in a manner that does

not discriminate against any shareholders. Further, rule 23c-2(b) (17 CFR 270.23c-2(b)) requires closed-end funds that propose to call or redeem any securities it has issued to file with the Commission notice of its intention at least 30 days prior to the date set for the call or redemption, provided that if such notice is required to be published in newspaper, notice is required within 10 days of publication. The notice is required to include (1) the title of the class of securities to be called or redeemed; (2) the date on which the securities are to be called or redeemed; (3) the applicable provisions of the governing instrument pursuant to which the securities are to be called or redeemed; and (4) if less than all the outstanding securities of a class or series are to be called or redeemed, the principal amount or number of shares and the basis upon which the securities to be call or redeemed are to be selected.

The Commission last submitted an information collection request ("ICR") regarding this rule to OMB for approval under the Paperwork Reduction Act of 1995 ("PRA") in November of 1982. The submission was subsequently approved in February of 1983. The Commission never sought an extension of the previously approved ICR upon expiration of the OMB approval in February of 1986. The reason the Commission never sought an extension is because the number of responses to this ICR recorded within the 1982 submission was only five, which is below the threshold of ten respondents outlined within the PRA for requiring OMB clearance. The Commission is now seeking to reinstate the rule 23c-2 ICR under control number 3235-0282.

Commission staff estimates that approximately 75 closed-end funds undertake an average of 110 proposed calls or redemptions of securities annually under rule 23c-2. Staff estimates further that, with respect to each proposed call or redemption, each fund spends 1.5 hours to comply with the rule's filing requirement with the Commission. Thus, Commission staff estimates the total annual respondent reporting burden is 165 hours. The total annual cost for all funds is estimated to be \$81,180.

The requirements of this collection of information are mandatory. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

The public may view and comment on this information collection request at: <https://www.reginfo.gov/public/do/>

[PRAViewICR?ref_nbr=202507-3235-015](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202507-3235-015) or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by December 29, 2025.

Dated: November 24, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21390 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104249; File No. SR-FICC-2025-022]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the FICC Rules To Align With Exchange Act Rule 17ad-26

November 24, 2025.

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 November 21, 2025, Fixed Income Clearing Corporation ("FICC") 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 clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(4) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of certain changes to Rule 17B (Wind-down of the Corporation) of the Clearing Rules of the Mortgage-Backed Securities Division ("MBSD," and its Clearing Rules, "MBSD Rules") of Fixed Income Clearing Corporation ("FICC"), and Rule 22D (Wind-down of the Corporation) of the rulebook of the Government Securities Division ("GSD," and its rulebook, "GSD Rules")⁵ of FICC to revise certain defined terms and make related technical changes to align with

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(4).

⁵ Terms not otherwise defined herein have the meaning set forth in the MBSD Rules and GSD Rules (collectively the "Rules"), available at www.dtcc.com/legal/rules-and-procedures.

Exchange Act Rule 17ad-26⁶ (“SEC Rule 17ad-26” or “Rule 17ad-26”) promulgated by the Commission.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission promulgated Rule 17ad-26,⁷ which requires that plans for the recovery and orderly wind-down of a covered clearing agency, such as FICC, include certain specific elements. The Commission recently approved FICC’s proposed rule change to reflect the requirements of Rule 17ad-26 in the FICC Recovery & Wind-down Plan (the “Plan” or “RWP”).⁸ For purposes of implementing certain aspects of the RWP, FICC is proposing to revise certain defined terms and make certain technical changes to MBSD Rule 17B (Wind-down of the Corporation)⁹ and GSD Rule 22D (Wind-down of the Corporation),¹⁰ in order to align with how they are referred to in the Plan and to conform with the definitions set forth in Rule 17ad-26.¹¹

A. Proposal To Modify or Add Certain Defined Terms in MBSD Rule 17B (Wind-Down of the Corporation) and GSD Rule 22D (Wind-Down of the Corporation)

(i) Proposal To Replace the Term “Critical Services” With “Core Services”

Consistent with SEC Rule 17ad-26(a)(1),¹² FICC is proposing to modify MBSD Rule 17B and GSD Rule 22D to replace all references to “Critical Services” with “Core Services.” Use of the descriptive term “Core” rather than “Critical” would not affect FICC’s identification, classification or description of these services in the RWP. Similarly, the proposed rule filing would replace all references to “Non-Critical Services” with “Non-Core Services.”

(ii) Proposal To Modify the Defined Terms “Recovery Plan” and “Wind-Down Plan”

For purposes of consistency with SEC Rule 17ad-26(b),¹³ FICC is proposing to capitalize references to the terms “Recovery” and “Orderly Wind-down,” and add an associated reference to the definition of these terms as set forth under SEC Rule 17ad-26(b)¹⁴ within

¹² *Id.* In the Adopting Release covering Rule 17ad-26, it was noted that “The Commission is modifying the final rule to refer to ‘core payment, clearance, and settlement services’ rather than ‘critical payment, clearance, and settlement services’ (hereinafter, referred to as ‘core services’) to improve clarity and consistency with terminology in other rules, such as Rule 17Ad-25(i), 242 which concerns the governance of ‘service providers for core services.’ Furthermore, the use of ‘core’ as opposed to ‘critical’ helps distinguish a CCA’s obligations under Rule 17Ad-26 from those under 17 CFR 242.1000 through 242.1007 (‘Regulation SCI’), which addresses, in the context of clearing agencies subject to the rule, ‘critical systems’ that support clearance and settlement. The Commission further noted that ‘Use of the descriptive term ‘core’ rather than ‘critical’ does not affect the Commission’s guidance stated in the RWP Proposing Release on identifying those services.’”

¹³ *Id.*

¹⁴ *Id.* Pursuant to SEC Rule 17ad-26(b), “Recovery” means the actions of a covered clearing agency, consistent with its rules, procedures, and other ex ante contractual arrangements, to address any uncovered loss, liquidity shortfall, or capital inadequacy, whether arising from participant default or other causes (such as business, operational, or other structural weaknesses), including actions to replenish any depleted prefunded financial resources and liquidity arrangements, as necessary to maintain the covered clearing agency’s viability as a going concern and to continue its provision of core services, as identified by the covered clearing agency pursuant to paragraph (a)(1) of this section.” The term “Orderly wind-down” means the actions of a covered clearing agency to effect the permanent cessation, sale, or transfer of one or more of its core services, as identified by the covered clearing agency pursuant to paragraph (a)(1) of this section, in a manner that would not increase the risk of

the definitions of “Recovery Plan” and “Wind-down Plan” in MBSD Rule 17B and GSD Rule 22D.

(iii) Proposal To Update Defined Terms “Member” and “Non-Eligible Member” in GSD Rule 22D (Wind-Down of the Corporation)

FICC is proposing to update the defined term “Member” in GSD Rule 22D by adding “Agent Clearing Member” to the list of GSD member types covered by this defined term. This proposed change is intended to be consistent with the changes recently approved by the Commission to GSD Rule 8 (Agent Clearing Service).¹⁵ FICC is also proposing to add at the end of the definition of “Non-Eligible Member,” a reference to SEC Rule 17ad-26 to supplement the existing reference to SEC Rule 17Ad-22(e)(3)(ii)¹⁶ as the relevant SEC rules concerning the Plan.

B. Implementation of the Proposal

As noted above, the principal purpose of the proposed rule change is to revise certain defined terms and make related technical changes to MBSD Rule 17B (Wind-down of the Corporation) and GSD Rule 22D (Wind-down of the Corporation) to align with Rule 17ad-26.¹⁷ This would help to facilitate implementation of certain aspects of the RWP in a manner consistent with SEC Rule 17ad-26¹⁸ and the amended RWP recently approved by the Commission.¹⁹ Based on the compliance date of SEC Rule 17ad-26 established by the Commission, the proposed rule change would become operative on December 15, 2025.²⁰

significant liquidity, credit, or operational problems spreading among financial institutions or markets and thereby threaten the stability of the U.S. financial system.

¹⁵ See Securities Exchange Act Release No. 101694 (Nov. 21, 2024), 89 FR 93784 (Nov. 27, 2024) (SR-FICC-2024-005) in which FICC proposes to re-name, consolidate, and adopt additional provisions governing GSD’s existing correspondent clearing/prime broker services. Moving forward, the correspondent clearing/prime broker services would be referred to as the “Agent Clearing Service.” Submitting Members would be referred to as “Agent Clearing Members,” and Executing Firms would be referred to as “Executing Firm Customers.” The Agent Clearing Service would continue to allow Netting Members to submit, on behalf of their customers, transactions to FICC for novation. These proposed changes would primarily amend GSD Rule 8, which currently describes the correspondent clearing/prime broker services, to describe the Agent Clearing Service with greater specificity.

¹⁶ 17 CFR 240.17ad-22(e)(3)(iii).

¹⁷ *Supra* note 6.

¹⁸ *Supra* note 6.

¹⁹ *Supra* note 8.

²⁰ *Supra* note 6. As set forth in the Adopting Release, “[. . .] (2) the proposed rule changes and Advance Notices must be effective by December 15, 2025. These compliance dates provide sufficient

⁶ Covered Clearing Agency Resilience and Recovery and Orderly Wind-down Plan, Exchange Act Release No. 101446 (Oct. 25, 2024), 89 FR 91000 (Nov. 18, 2024) (S7-10-23).

⁷ *Id.*

⁸ See Securities Exchange Act Release No. 103221 (June 10, 2025), 90 FR 25414 (June 16, 2025) (SR-FICC-2025-010).

⁹ MBSD Rule 17B (Wind-down of the Corporation), *supra* note 5.

¹⁰ GSD Rule 22D (Wind-down of the Corporation), *supra* note 5.

¹¹ *Supra* note 6.

2. Statutory Basis

FICC believes that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, FICC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,²¹ Rule 17ad–22(e)(3)(ii) under the Act,²² and Rule 17ad–26 under the Act²³ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the MBSD Rules and GSD Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.²⁴ The proposed rule change would help to ensure that the Rules are accurate and clear to participants in the event that the RWP is ever needed to be implemented by FICC. When participants better understand their rights and obligations regarding the Rules, such participants are more likely to act in accordance with the Rules, which FICC believes would promote the prompt and accurate clearance and settlement of securities transactions. As such, FICC believes that the proposed changes would be consistent with Section 17A(b)(3)(F) of the Act.²⁵ Further, by providing clarity on the Rules covering a FICC recovery and orderly wind-down, the proposed rule change would help ensure the continuity of FICC's core functions for the markets served by FICC, and thereby promote the prompt and accurate clearance and settlement of securities transactions.

Rule 17ad–22(e)(3)(ii) under the Act requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business

risk, or any other losses.²⁶ By ensuring that defined terms in the relevant Rules are consistent with how such terms are defined under Rule 17ad–26 and how they are referred to in the Plan, FICC believes that the proposed rule change is designed to support the maintenance of the and, as such, meets the requirements of Rule 17ad–22(e)(3)(ii) under the Act. Therefore, the proposed changes would help FICC to maintain the Plan in a way that continues to be consistent with the requirements of Rule 17ad–22(e)(3)(ii).²⁷

In addition to the requirements covering elements to be included in the recovery and wind-down plans of covered clearing agencies, SEC Rule 17ad–26 includes certain associated new defined terms.²⁸ The proposed rule change would revise certain defined terms and make related technical changes to the applicable Rules to align with SEC Rule 17ad–26. By doing so, FICC believes that the proposed rule change would help FICC maintain the Plan and the Rules in a way that is consistent with Rule 17ad–26.²⁹

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe the proposed rule changes to revise certain defined terms and make related technical changes to align with SEC Rule 17ad–26 promulgated by the Securities and Exchange Commission would impact competition. The proposed rule changes would help to ensure that the Rules remain clear and accurate. In addition, the changes would facilitate participants' understanding of the Rules and their obligations thereunder. These changes would not affect FICC's operations or the rights and obligations of the membership. As such, FICC believes the proposed rule changes would not have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the

Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at* www.sec.gov/rules-regulations/how-submit-comment. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at tradingandmarkets@sec.gov or 202–551–5777.

FICC reserves the right to not respond to any comments 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)³⁰ of the Act and paragraph (f) of Rule 19b–4 thereunder.³¹ 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 will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–FICC–2025–022 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

time for CCAs to consider changes to their rules, policies, and procedures necessary to ensure consistency with the rules amended and adopted in this release [. . .].”

²¹ 15 U.S.C. 78q–1(b)(3)(F).

²² See 17 CFR 240.17ad–22(e)(3)(ii). FICC is a “covered clearing agency” as defined in Rule 17ad–22(a)(5) under the Act and must comply with paragraph (e) of Rule 17ad–22. In 2012, FICC was designated a Systemically Important Financial Market Utility by the Financial Stability Oversight Council.

²³ *Supra* note 6.

²⁴ 15 U.S.C. 78q–1(b)(3)(F).

²⁵ *Id.*

²⁶ 17 CFR 240.17ad–22(e)(3)(ii).

²⁷ *Id.*

²⁸ *Supra* note 6.

²⁹ *Id.*

³⁰ 15 U.S.C. 78s(b)(3)(A).

³¹ 17 CFR 240.19b–4(f).

All submissions should refer to file number SR-FICC-2025-022. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of FICC and on DTCC's website (<https://dtcc.com/legal/sec-rule-filings.aspx>). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-FICC-2025-022 and should be submitted on or before DECEMBER 19, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-21403 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104251; File No. SR-NYSEARCA-2025-39]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To Adopt New Rule 5.2-E(j)(9) To Permit the Generic Listing and Trading of Class Exchange-Traded Fund Shares

November 24, 2025.

On May 28, 2025, NYSE Arca, Inc. ("NYSE Arca" 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 to adopt new Rule 5.2-E(j)(9) to permit the generic listing and trading of Class Exchange-Traded Fund Shares. The proposed rule change was published for comment in the **Federal Register** on June 10, 2025.³

On July 15, 2025, pursuant to 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 September 4, 2025, the Exchange filed Amendment No. 1 to the proposed rule change, and on September 5, 2025, the Commission issued notice of filing of Amendment No. 1 to the proposed rule change and instituted proceedings pursuant to Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.⁷ On November 19, 2025, the Exchange filed Amendment No. 2, which amended and replaced the proposed rule change, as modified by Amendment No. 1, in its entirety.⁸ The Commission has received no comments regarding the proposed rule change.

The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 2, from interested persons and to grant approval of the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

I. The Exchange's Description of the Proposal, as Modified by Amendment No. 2

The Exchange proposes to (1) adopt a new Rule 5.2-E(j)(9) to permit the generic listing and trading of Class Exchange-Traded Fund ("ETF") Shares, and (2) make certain conforming changes to the Exchange's rules to accommodate the proposed listing of Class ETF Shares. This Amendment No. 2 to SR-NYSEARCA-2025-39 replaces SR-NYSEARCA-2025-39 and Amendment No. 1 thereto as originally filed and supersedes such filings in their entirety.

The proposed rule change is available on the Exchange's website at www.nyse.com and 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to (1) adopt a new Rule 5.2-E(j)(9) to permit the generic listing and trading, or trading pursuant to unlisted trading privileges, of Class ETF Shares; and (2) make certain conforming changes to the Exchange's rules to accommodate the proposed listing of Class ETF Shares.⁹

Consistent with other products (specifically, Investment Company Units listed pursuant to Rule 5.2-E(j)(3), Managed Fund Shares listed pursuant to Rule 8.600-E, and ETF Shares listed pursuant to Rule 5.2-E(j)(8)), Class ETF Shares would be permitted to be listed and traded on the Exchange without prior Commission approval order or notice of effectiveness pursuant to Section 19(b) of the Act.¹⁰

⁹ The Exchange notes that Cboe BZX Exchange, Inc. ("BZX") and The Nasdaq Stock Market LLC ("Nasdaq") have filed substantially similar rule filings. See Securities Exchange Act Release Nos. 103188 (June 4, 2025), 90 FR 24457 (June 10, 2025) (SR-CboeBZX-2025-076) & 103072 (May 20, 2025), 90 FR 22373 (May 27, 2025) (SR-NASDAQ-2025-037).

¹⁰ Rule 19b-4(e)(1) provides that the listing and trading of a new derivative securities product by a self-regulatory organization ("SRO") is not deemed a proposed rule change, pursuant to paragraph (c)(1) of Rule 19b-4, if the Commission has approved, pursuant to Section 19(b) of the Act, the SRO's trading rules, procedures and listing standards for the product class that would include the new derivative securities product and the SRO has a surveillance program for the product class. As contemplated by proposed Rule 5.2-E(j)(9), the Exchange proposes to establish generic listing standards for Class ETF Shares of the ETF Class (as defined herein) that would be required to operate as an ETF pursuant to the Multi-Class Fund Exemptive Relief (as defined herein) and be in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act of 1940 (the "Investment Company Act"), except as noted in the Multi-Class Fund Exemptive Relief. Class ETF Shares listed under proposed Rule 5.2-E(j)(9) would therefore not need a separate proposed rule change pursuant to Rule 19b-4 before it can be listed and traded on the Exchange.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 103457, 90 FR 34044 (July 18, 2025).

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 103885, 90 FR 43655 (Sept. 10, 2025).

⁸ Amendment No. 2 to the proposed rule change is available on the Commission's website at: <https://www.sec.gov/comments/sr-nysearca-2025-39/srnysearca202539-677567-2074914.pdf>.

³² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 103189 (June 4, 2025), 90 FR 24463.

Background

There are numerous applications for exemptive relief for Class ETF Shares currently before the Commission¹¹ requesting exemptive relief similar to that previously granted to other funds.¹² The current proposal would provide for the “generic” listing and/or trading of Class ETF Shares under proposed Rule 5.2–E(j)(9) on the Exchange.

The Commission began granting limited relief for The Vanguard Group, Inc. (“Vanguard”) in 2000 to offer certain index-based open-end management investment companies with Class ETF Shares.¹³ After this relief was granted, there was limited public discourse about Class ETF Shares until 2019, when the prospect of providing blanket exemptive relief to Class ETF Shares was addressed in the Commission’s adoption of Rule 6c–11 under the Investment Company Act (the “ETF Rule”).¹⁴ The ETF Rule permits ETFs that satisfy certain conditions to operate without the expense or delay of obtaining an exemptive order. However, the ETF Rule did not provide blanket exemptive relief to allow for Class ETF Shares as part of the final rule. Instead, the Commission concluded that Class ETF Shares should request relief through the exemptive application

process so that the Commission may assess all relevant policy considerations in the context of the facts and circumstances of particular applicants. The Exchange adopted Rule 5.2–E(j)(8)¹⁵ shortly after implementation of the ETF Rule and, because the ETF Rule did not provide blanket relief to the Class ETF Shares listed on the Exchange pursuant to previously granted exemptive relief and there were no exemptive applications before the Commission at that time, the Exchange did not propose to include any language comparable to what is being proposed herein.

As noted, a number of applications for exemptive relief to permit the applicable fund to offer Class ETF Shares (the “Applications”) have been submitted to the Commission starting in early 2023. In general, the Applications state that the ability of a fund to offer Class ETF Shares, *i.e.*, a fund offering both a class of mutual fund shares and a class of shares that are exchange-traded, could be beneficial to the fund and to shareholders of each type of class for various reasons, including more efficient portfolio management, better secondary market trading opportunities, and cost efficiencies, among others.¹⁶ The Commission has granted, by order, specific exemptive relief (“Multi-Class Fund Exemptive Relief”) under the Investment Company Act on November 17, 2025, that permits, subject to certain conditions and requirements, a Multi-Class Fund (as defined below) to issue Class ETF Shares (as defined below) and one or more classes of shares that are not exchange traded, among other things.¹⁷

Proposed Rule Change

Proposed Rule 5.2–E(j)(9)

Proposed Rule 5.2–E(j)(9) is modeled on current Rule 5.2–E(j)(8).

Rule 5.2–E(j)(9)(a) would provide that the Exchange will consider for trading, whether by listing or pursuant to unlisted trading privileges, Class ETF Shares that meet the criteria of the proposed rule.¹⁸

¹⁵ See Securities Exchange Act No. 88625 (April 13, 2020) 85 FR 21479 (April 17, 2020) (SR–NYSEArca–2019–81) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, to Adopt NYSE Arca Rule 5.2–E(j)(8) Governing the Listing and Trading of ETF Shares).

¹⁶ See note 11, *supra*.

¹⁷ See Investment Company Act Release No. 35786 (November 17, 2025) (In the Matter of DFA Investment Dimensions Group Inc., Dimensional Investment Group Inc., Dimensional ETF Trust and Dimensional Fund Advisors LP) (File No. 812–15484).

¹⁸ To the extent that Class ETF Shares do not satisfy one or more of the criteria in proposed Rule

Proposed Rule 5.2–E(j)(9)(b) titled “Applicability” would provide that the proposed rule would be applicable only to Class ETF Shares. Except to the extent inconsistent with proposed Rule 5.2–E(j)(9), or unless the context otherwise requires, the rules and procedures of the Board of Directors shall be applicable to the trading on the Exchange of such securities. Class ETF Shares are included within the definition of “security” or “securities” as such terms are used in the Rules of the Exchange.

Proposed Rule 5.2–E(j)(9)(c) titled “Definitions” would set forth the meanings of terms as used in the Rule unless the context otherwise requires.

Proposed Rule 5.2–E(j)(9)(c)(1) would provide that the term “Class ETF Shares” means shares of the ETF Class issued by a Multi-Class Fund.

Proposed Rule 5.2–E(j)(9)(c)(2) would provide that the term “ETF Class” means the class of exchange-traded shares of a Multi-Class Fund that (i) operates as an exchange-traded fund pursuant to exemptive relief granted by order under the Investment Company Act (“Multi-Class Fund Exemptive Relief”), and (ii) is in compliance with the requirements of Rules 5.2–E(j)(9)(e)(1)(ii) and 5.2–E(j)(9)(e)(2)(A)(ii) discussed below on an initial and continued listing basis.

Proposed Rule 5.2–E(j)(9)(c)(3) would provide that the term “Multi-Class Fund” means a registered open-end management company that (i) pursuant to Multi-Class Fund Exemptive Relief, issues Class ETF Shares and one or more classes of shares that are not exchange traded, and (ii) is in compliance with the conditions and requirements of the Multi-Class Fund Exemptive Relief.

Proposed Rule 5.2–E(j)(9)(c)(4) would provide that the term “Reporting

5.2–E(j)(9), the Exchange may file a separate proposal under Section 19(b) of the Act in order to list such securities on the Exchange. Any of the statements or representations in that proposal regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index, reference asset, and intraday indicative values (as applicable), or the applicability of Exchange listing rules specified in any filing to list such Class ETF Shares shall constitute continued listing requirements for the Class ETF Shares. Further, in the event that Class ETF Shares become listed under proposed Rule 5.2–E(j)(9) and subsequently can no longer satisfy the requirements of proposed Rule 5.2–E(j)(9), such Class ETF Shares may be listed as Investment Company Units pursuant to Rule 5.2–E(j)(3) or Managed Fund Shares under Rule 8.600–E, as applicable, as long as the Class ETF Shares meet all listing requirements applicable under the alternate listing rule. If the Class ETF Shares do change listing standards, the Exchange would have to comply with all requirements of Rule 19b–4(e) with respect to such Class ETF Shares.

¹¹ See DFA Investment Dimensions Group Inc. and Dimensional Investment Group Inc., (amendment filed March 31, 2025); F/m Investments LLC (amendment filed April 10, 2025); Fidelity Hastings Street Trust and Fidelity Management & Research Company (amendment filed April 11, 2025); Morgan Stanley Institutional Fund Trust and Morgan Stanley Investment Management Inc. (amendment filed April 11, 2025); BlackRock Funds (amendment filed April 15, 2025); Guinness Atkinson Funds (amendment filed April 17, 2025); Metropolitan West Funds, TCW ETF Trust, and TCW Funds, Inc. (amendment filed April 22, 2025); and Northern Funds and Northern Trust Investments, Inc. (amendment filed May 2, 2025).

¹² See note 13, *infra*.

¹³ See Vanguard Index Funds, Investment Company Act Release Nos. 24680 (Oct. 6, 2000) (notice) and 24789 (Dec. 12, 2000) (order). The Commission itself, as opposed to the Commission staff acting under delegated authority, considered the original Vanguard application and determined that the relief was appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Investment Company Act. In the process of granting the order, the Commission also considered and denied a hearing request on the original application, as reflected in the final Commission order. See also the Vanguard Group, Inc., Investment Company Act Release Nos. 26282 (Dec. 2, 2003) (notice) and 26317 (Dec. 30, 2003) (order); Vanguard International Equity Index Funds, Investment Company Act Release Nos. 26246 (Nov. 3, 2003) (notice) and 26281 (Dec. 1, 2003) (order); Vanguard Bond Index Funds, Investment Company Act Release Nos. 27750 (Mar. 9, 2007) (notice) and 27773 (April 2, 2007) (order) (collectively referred to as the “Vanguard Orders”).

¹⁴ See Securities Exchange Act Release No. 10695 (September 25, 2019), 84 FR 57162 (October 24, 2019) (the “ETF Rule Adopting Release”).

Authority” in respect of a particular Multi-Class Fund means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists Class ETF Shares (if the Exchange is trading such securities pursuant to unlisted trading privileges) as the official source for calculating and reporting information relating to such Multi-Class Fund, including, but not limited to, the amount of any dividend equivalent payment or cash distribution to holders of Class ETF Shares, net asset value, index or portfolio value, the current value of the portfolio of securities required to be deposited in connection with the issuance of Class ETF Shares, or other information relating to the issuance, redemption or trading of Class ETF Shares. A Multi-Class Fund may have more than one Reporting Authority, each having different functions.

Proposed Rule 5.2–E(j)(9)(d) titled “Limitation of Exchange Liability” would provide that neither the Exchange, the Reporting Authority, nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the Multi-Class Fund in connection with the issuance of Class ETF Shares; the amount of any dividend equivalent payment or cash distribution to holders of Class ETF Shares; net asset value; or other information relating to the purchase, redemption, or trading of Class ETF Shares, resulting from any negligent act or omission by the Exchange, the Reporting Authority, or any agent of the Exchange, or any act, condition, or cause beyond the reasonable control of the Exchange, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

Proposed Rule 5.2–E(j)(9)(e) would provide that the Exchange may approve Class ETF Shares of a Multi-Class Fund for listing and/or trading (including pursuant to unlisted trading privileges) pursuant to Rule 19b–4(e) of the Act. For each listed Class ETF Shares, the ETF Class and the Multi-Class Fund issuing the Class ETF Shares, as applicable, must satisfy the requirements of Rule 5.2–E(j)(9) upon initial listing and, except for

subparagraph (1)(A) of Rule 5.2–E(j)(9)(e), on a continuing basis. An issuer of such securities must notify the Exchange of any failure to comply with such requirements.

Proposed Rule 5.2–E(j)(9)(e)(1) titled “Initial and Continued Listing” would provide that Class ETF Shares will be listed and traded on the Exchange provided that: (i) the Multi-Class Fund is eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (ii) the ETF Class is in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of this Rule, as applicable, on an initial and continued listing basis. Proposed Rule 5.2–E(j)(9)(e)(1)(A), titled “Initial Shares Outstanding,” would provide that the Exchange will establish a minimum number of Class ETF Shares required to be outstanding at the time of commencement of trading on the Exchange.

Proposed Rule 5.2–E(j)(9)(e)(2) titled “Suspension of trading or removal” would provide that the Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 5.5–E(m) of Class ETF Shares under any of the following circumstances:

- if the Exchange becomes aware that with respect to the Class ETF Shares: (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (ii) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief;
- if any of the other listing requirements set forth in proposed Rule 5.2–E(j)(9) are not continuously maintained (proposed Rule 5.2–E(j)(9)(e)(2)(B));
- if, following the initial twelve-month period after commencement of trading on the Exchange of Class ETF Shares, there are fewer than 50 beneficial holders of Class ETF Shares (proposed Rule 5.2–E(j)(9)(e)(2)(C)); or
- if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable (proposed Rule 5.2–E(j)(9)(e)(2)(D)).

Proposed Rule 5.2–E(j)(9)(f) would provide that transactions in Class ETF Shares will occur during the trading hours specified in Rule 7.34–E(a).

Proposed Rule 5.2–E(j)(9)(g) titled “Surveillance Procedures” would provide that the Exchange will implement and maintain written surveillance procedures for Class ETF Shares.

Proposed Rule 5.2–E(j)(9)(h) titled “Termination” would provide that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing.

The Exchange proposes to add Commentary .01 to proposed Rule 5.2–E(j)(9). Proposed Commentary .01 to Rule 5.2–E(j)(9) would provide that the following requirements shall be met by Class ETF Shares on an initial and continued listing basis.

Subsection (a)(1) of proposed Commentary .01 would provide that with respect to Class ETF Shares based on an index, if the underlying index is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser will erect and maintain a “fire wall” around the personnel who have access to information concerning changes and adjustments to the index and the index will be calculated by a third party who is not a broker-dealer or fund adviser.

Subsection (a)(2) of proposed Commentary .01 would provide that any advisory committee, supervisory board, or similar entity that advises a Reporting Authority (as defined in the proposed rule) or that makes decisions on the index composition, methodology and related matters, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index.

Subsection (b) of proposed Commentary .01 would provide that with respect to a Multi-Class Fund that is actively managed, if the investment adviser to the Multi-Class Fund issuing Class ETF Shares is affiliated with a broker-dealer, such investment adviser will erect and maintain a “fire wall” between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Multi-Class Fund’s portfolio. Further, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the

applicable portfolio. The Reporting Authority that provides information relating to the Multi-Class Fund's portfolio must also implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the actual components of such portfolio.

Proposed Conforming Changes

The Exchange also proposes corresponding amendments to include Class ETF Shares in other Exchange rules, which are intended to align the treatment of the proposed products with how other open-end management investment company shares (*e.g.*, Investment Company Units, Managed Fund Shares, and ETF Shares) are treated under the Exchange's rules.

First, the Exchange proposes to add Class ETF Shares to the definition of "Derivative Securities Product and UTP Derivative Securities Product" in Rule 1.1.

Second, the Exchange proposes to amend Rule 5.3–E to exempt Class ETF Shares from the requirements of Rule 5.3–E(d)(9) in connection with the acquisition of the stock or assets of an affiliated registered investment company in a transaction that complies with Rule 17a–8 under the Investment Company Act and does not otherwise require shareholder approval under the Investment Company Act¹⁹ and the rules thereunder or any other Exchange rule.²⁰ In addition, the Exchange proposes to add proposed Rule 5.2–E(j)(9) to the last paragraph of Rule 5.3–E, which defines derivative and special purpose securities for purposes of Rule 5.3–E.

Discussion

Proposed Rule 5.2–E(j)(9) is based in large part on Rule 5.2–E(j)(8) related to the listing and trading of ETF Shares, which are issued under the Investment Company Act and qualify as ETF Shares under Rule 6c–11 under the Investment Company Act. ETF Shares are similar to Class ETF Shares because the ETF Class is required to operate as an ETF pursuant to the Multi-Class Fund Exemptive Relief and be in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act (except as noted in the

Multi-Class Fund Exemptive Relief).²¹ The proposed Class ETF Shares generic listing rule would apply only to the class of shares that are exchange-traded. Because the ETF Class would be required to comply, among other things, with the conditions and requirements of Rule 6c–11 under the Investment Company Act, similar to ETF Shares under Rule 5.2–E(j)(8), the Exchange believes that using Rule 5.2–E(j)(8) as the basis for proposed Rule 5.2–E(j)(9) is appropriate.

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices because the Exchange will perform ongoing surveillance of Class ETF Shares listed on the Exchange in order to ensure (i) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of the proposed Rule, as applicable, on an initial and continuing basis. The Exchange believes that the manipulation concerns that such standards are intended to address are otherwise mitigated by a combination of the Exchange's surveillance procedures, the Exchange's ability to halt trading and to suspend trading and commence delisting proceedings under proposed Rule 5.2–E(j)(9)(e)(2). The Exchange will also halt trading in Class ETF Shares under the conditions specified in Rule 7.12–E, "Trading Halts Due to Extraordinary Market Volatility." The Exchange also believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that have come from Rule 6c–11 under the Investment Company Act, specifically the additional flexibility provided through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c–11.²² The Exchange also notes that there are firewall and other information barrier

restrictions in place in the proposed rule text.²³ The Exchange believes that the combination of these factors will act to keep Class ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of Class ETF Shares on the Exchange.

The Exchange will monitor for compliance to ensure that (i) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is in otherwise in compliance with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of Rule 5.2–E(j)(9), as applicable, on an initial and continuing basis. Specifically, the Exchange will review the website of Class ETF Shares listed on the Exchange in order to ensure that the requirements of Rule 6c–11 are being met. The Exchange will also employ numerous intraday alerts that will notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain disclosures not being made timely or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. As a backstop to the surveillances described above, the Exchange also notes that Rule 5.2–E(j)(9) would require an issuer of Class ETF Shares to notify the Exchange of any failure to comply with the requirements of the proposed Rule, the Multi-Class Fund Exemptive Relief, or Rule 6c–11 under the Investment Company Act.

The Exchange may suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable.²⁴ The Exchange also notes

²³ See proposed Rule 5.2–E(j)(9), Commentary .01(a)(1) & (2).

²⁴ Specifically, proposed Rule 5.2–E(j)(9)(e)(1) provides that Class ETF Shares will be listed and traded on the Exchange subject to application of proposed Rule 5.2–E(j)(9)(e)(2). Proposed Rule 5.2–E(j)(9)(e)(2) provides that the Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 5.5(m) for, Class ETF Shares under any of the following circumstances: (i) if the Exchange becomes aware, with respect to the Class ETF Shares: (1) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive

¹⁹ The Exchange also proposes non-substantive, technical changes to delete two extraneous words in this rule.

²⁰ The Exchange notes that these proposed changes would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange.

²¹ See note 17, *supra*.

²² The Exchange notes that the Commission came to a similar conclusion in several places in the ETF Rule Adopting Release. See ETF Rule Adopting Release at 15–18; 60–61; 69–70; 78–79; 82–84; and 95–96.

that proposed Rule 5.2–E(j)(9)(e) requires any issuer to provide the Exchange with prompt notification after it becomes aware that: (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or otherwise no longer complies with, the terms and conditions of, the Multi-Class Fund Exemptive Relief; (ii) the ETF Class is no longer compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; or (iii) the ETF Class or the Multi-Class Fund no longer satisfies the requirements of proposed Rule 5.2–E(j)(9), as applicable, on an initial and continuing basis.²⁵

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the Class ETF Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, Managed Fund Shares, and ETF Shares, among other product types, to monitor trading in Class ETF Shares on the Exchange. The Exchange or the Financial Industry Regulatory Authority, Inc. (“FINRA”), on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the Intermarket Surveillance Group (“ISG”) or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding

Relief; or (2) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; (ii) if any of the other listing requirements set forth in this Rule are not continuously maintained; (iii) if, following the initial twelve-month period after commencement of trading on the Exchange of Class ETF Shares, there are fewer than 50 beneficial holders of such the Class ETF Shares; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 5.2–E(j)(9)(h) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that Class ETF Shares be removed from Exchange listing.

²⁵ The Exchange notes that failure by an issuer to notify the Exchange of non-compliance pursuant to proposed Rule 5.2–E(j)(9)(e) would itself be considered non-compliance with the requirements of Rule 5.2–E(j)(9) and would subject the Class ETF Shares to potential trading halts and the delisting process under Rule 5.5(m).

trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access trade information for certain fixed income securities that may be held by a Multi-Class Fund for the Class ETF Shares reported to FINRA’s Trade Reporting and Compliance Engine (“TRACE”). FINRA also can access data obtained from the Municipal Securities Rulemaking Board’s (“MSRB”) Electronic Municipal Market Access (“EMMA”) system relating to municipal bond trading activity for surveillance purposes in connection with trading in Class ETF Shares, to the extent that the Multi-Class Fund for the Class ETF Shares holds municipal securities. Finally, the issuer of Class ETF Shares will be required to comply with Rule 10A–3 under the Act for the initial and continued listing of Class ETF Shares, as provided under Rule 5.3–E.²⁶

The Exchange notes that it may consider all relevant factors in exercising its discretion to halt or suspend trading in Class ETF Shares. Trading may be halted if the circuit breaker parameters in Rule 7.12–E have been reached, because of other market conditions, or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) the extent to which certain information about the Class ETF Shares that is required to be disclosed under Rule 6c–11 under the Investment Company Act is not being made available, including specifically where the Exchange becomes aware that the net asset value or the daily portfolio disclosure with respect to Class ETF Shares is not disseminated to all market participants at the same time, it will halt trading in such securities until such time as the net asset value or the daily portfolio disclosure is available to all market participants;²⁷ (2) if an interruption to the dissemination to the value of the index or reference asset on which Class ETF Shares is based persists past the trading day in which it

²⁶ The Exchange notes that these proposed changes would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange.

²⁷ The Exchange will obtain a representation from the issuer of Class ETF Shares that the net asset value per share will be calculated daily and made available to all market participants at the same time, and the requirements pertaining to the Multi-Class Fund Exemptive Relief and Rule 6c–11 under the Investment Company Act in proposed Rule 5.2–E(j)(9) will be satisfied.

occurred or is no longer calculated or available; (3) trading in the securities comprising the underlying index or portfolio has been halted in the primary market(s); or (4) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.

The Exchange deems Class ETF Shares to be equity securities and therefore they would be subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.²⁸

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,²⁹ in general, and furthers the objectives of Section 6(b)(5),³⁰ in that 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.

The Exchange believes that proposed Rule 5.2–E(j)(9) is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading Class ETF Shares on the Exchange provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 5.2–E(j)(9)(e) sets forth initial and continued listing criteria applicable to Class ETF Shares, specifically providing that the Exchange may approve Class ETF Shares for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b–4(e) under the Act, provided that (i) the Multi-Class Fund is eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (ii) the ETF Class is in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of this Rule, as

²⁸ With respect to trading in Class ETF Shares, the Exchange represents that all ETP Holder obligations relating to product description and prospectus delivery requirements will continue to apply in accordance with the Exchange’s rules and federal securities laws, and the Exchange will continue to monitor ETP Holders for compliance with such requirements, which are not changing as a result of the Multi-Class Fund Exemptive Relief order issued under the Investment Company Act.

²⁹ 15 U.S.C. 78f(b).

³⁰ 15 U.S.C. 78f(b)(5).

applicable, on an initial and continued listing basis.³¹ The Exchange will comply with all the requirements of Rule 19b-4(e) to specifically note that such Class ETF Shares are being listed on the Exchange pursuant to the proposed Rule.

Proposed Rule 5.2-E(j)(9)(e) provides that Class ETF Shares of each Multi-Class Fund will be listed and traded on the Exchange subject to application of proposed Rule 5.2-E(j)(9)(e)(2).

Proposed Rule 5.2-E(j)(9)(e)(2) provides that the Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 5.5(m) of, Class ETF Shares under any of the following circumstances:

- if the Exchange becomes aware with respect to the Class ETF Shares: (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or is otherwise no longer in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; or (ii) the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief;
- if any of the other listing requirements set forth in proposed Rule 5.2-E(j)(9) are not continuously maintained;
- if, following the initial twelve-month period after commencement of trading on the Exchange of the Class ETF Shares, there are fewer than 50 beneficial holders of Class ETF Shares; or
- if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

The Exchange notes that issuers are required to notify the Exchange of any non-compliance with Rule 6c-11 under the Investment Company Act or any applicable exemptive relief thereunder, as described in proposed Rule 5.2-

E(j)(9)(e)(1). Moreover, the Exchange may identify non-compliance through its own monitoring process.

Proposed Rule 5.2-E(j)(9)(h) provides that with respect to the Class ETF Shares, upon termination of the Multi-Class Fund or the ETF Class, as the case may be, the Exchange requires that the Class ETF Shares be removed from Exchange listing. The Exchange also notes that it will obtain a representation from the issuer of Class ETF Shares stating that the requirements of Rule 6c-11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied and that the issuer will notify the Exchange of any failure to do so.

The Exchange further believes that proposed Rule 5.2-E(j)(9) is designed to prevent fraudulent and manipulative acts and practices because of the robust surveillances in place on the Exchange as required under proposed Rule 5.2-E(j)(9)(g) along with the similarities of proposed Rule 5.2-E(j)(9) to the rules related to other securities that are already listed and traded on the Exchange and which would qualify as Class ETF Shares. ETF Shares are identical to Class ETF Shares except that Class ETF Shares have received exemptive relief to operate an exchange-traded fund class in addition to classes of shares that are not exchange-traded. As such, the Exchange believes because the ETF Class would be required to comply, among other things, with the conditions and requirements of Rule 6c-11 under the Investment Company Act, similar to ETF Shares under Rule 5.2-E(j)(8), using Rule 5.2-E(j)(8) as the basis for proposed Rule 5.2-E(j)(9) is appropriate.

The Exchange believes that the proposal is consistent with Section 6(b)(1) of the Act³² in that, in addition to being designed to prevent fraudulent and manipulative acts and practices, the Exchange has the capacity to enforce proposed Rule 5.2-E(j)(9) by performing ongoing surveillance of Class ETF Shares listed on the Exchange in order to ensure that (i) the Multi-Class Fund is, and continues to be, eligible to operate an ETF Class as an exchange-traded fund pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c-11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief, and (iii) the ETF Class and the Multi-Class Fund each satisfies the requirements of proposed

Rule 5.2-E(j)(9), as applicable, on an initial and continuing basis. The Exchange believes that the manipulation concerns that such standards are intended to address are otherwise mitigated by a combination of the Exchange's surveillance procedures, and the Exchange's ability to halt trading and to suspend trading and commence delisting proceedings under proposed Rule 5.2-E(j)(9)(e)(2). The Exchange will also halt trading in Class ETF Shares under the conditions specified in Rule 7.12-E, "Trading Halts Due to Extraordinary Market Volatility." The Exchange also believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that have come from compliance with Rule 6c-11, specifically the additional flexibility provided through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c-11 under the Investment Company Act.³³ The Exchange believes that the combination of these factors will act to keep Class ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of Class ETF Shares on the Exchange.

The Exchange will monitor for compliance with Rule 6c-11 and any applicable exemptive relief in order to ensure that the continued listing standards are being met. Specifically, the Exchange plans to review the website of Class ETF Shares in order to ensure that the requirements of Rule 6c-11 are being met. The Exchange will also employ numerous intraday alerts that will notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. As a backstop to the surveillances described above, the Exchange also notes that Rule 5.2-E(j)(9) requires an issuer of Class ETF Shares to promptly notify the Exchange of any failure to comply with Rule 6c-11 or the requirements of the Multi-Class Fund Exemptive Relief under the Investment Company Act.

To the extent that any of the requirements under Rule 6c-11 or the Multi-Class Fund Exemptive Relief

³¹ The Exchange notes that eligibility to operate in reliance on Rule 6c-11 or any applicable exemptive relief under the Investment Company Act does not necessarily mean that an investment company would be listed on the Exchange pursuant to proposed Rule 5.2-E(j)(9). To this point, an investment company that operates in reliance of exemptive relief providing for Class ETF Shares could alternatively be listed as Investment Company Units or Managed Fund Shares pursuant to Rules 5.2-E(j)(3) or 8.600-E, respectively, and would be subject to all requirements under each of those rules. Further to this point, in the event that Class ETF Shares listed on the Exchange preferred to be listed as a series of Investment Company Units or Managed Fund Shares (as applicable), nothing would preclude such security from changing to be listed as Investment Company Units or Managed Fund Shares (as applicable), as long as the security met each of the initial and continued listing obligations under the applicable rules.

³² 15 U.S.C. 78f(b)(1).

³³ The Exchange notes that the Commission came to a similar conclusion in several places in the ETF Rule Adopting Release. See ETF Rule Adopting Release at 15-18; 60-61; 69-70; 78-79; 82-84; and 95-96.

under the Investment Company Act are not being met, the Exchange may halt trading in Class ETF Shares as provided in proposed Rule 5.2–E(j)(9)(e). Further, the Exchange may also suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable. As discussed above, the Exchange also notes that proposed Rule 5.2–E(j)(9) requires any issuer to provide the Exchange with prompt notification after it becomes aware of any non-compliance with the proposed rule, which would include any failure of the issuer to comply with Rule 6c–11 or the Multi-Class Fund Exemptive Relief under the Investment Company Act.

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the Class ETF Shares in all trading sessions and to deter and detect violations of Exchange rules. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, Managed Fund Shares, and ETF Shares, among other product types, to monitor trading in Class ETF Shares. The Exchange or FINRA, on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Additionally, FINRA, on behalf of the Exchange, is able to access trade information for certain fixed income securities that may be held by the Multi-Class Fund for the Class ETF Shares reported to FINRA's TRACE. FINRA also can access data obtained from the MSRB's EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in Class ETF Shares, to the extent that the Multi-Class Fund for the Class ETF Shares holds municipal securities. Finally, as noted above, the issuer of Class ETF Shares will be required to comply with Rule 10A–3 under the Act for the initial and

continued listing of Class ETF Shares, as provided under Rule 5.3–E.

The Exchange believes that permitting Class ETF Shares to list on the Exchange will help perfect the mechanism of a free and open market and, in general, will protect investors and the public interest in that it will permit the listing and trading of Class ETF Shares, consistent with the applicable exemptive relief, and in a manner that will benefit investors. Specifically, the Exchange believes that the relief proposed in the Applications and the expected benefits of the Class ETF Shares described above would be to the benefit of investors.

The Exchange also believes that proposed Rule 5.2–E(j)(9) provisions which explicitly provide the initial and continued listing standards applicable to Class ETF Shares, including the suspension of trading or removal standards, are designed to promote transparency and clarity in the Exchange's Rules.

The Exchange also believes that the corresponding changes to add Class ETF Shares in the Exchange's corporate governance requirements under Rule 1.1 and Rule 5.3–E discussed above will add clarity to the Exchange's rulebook. Investment Company Units, Managed Fund Shares, and ETF Shares are similarly included in these provisions. Therefore, the Exchange believes these are non-substantive changes meant only to subject Class ETF Shares to the same exemptions and provisions currently applicable to Investment Company Units, Managed Fund Shares, and ETF Shares so that the treatment of these open-end management investment companies is consistent under the Exchange's rules.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposal, by permitting the listing and trading of Class ETF Shares under exemptive relief from the Investment Company Act and the rules and regulations thereunder, would introduce additional competition among various ETF products to the benefit of investors.

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. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.³⁴ In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(5) of the Act,³⁵ which requires, among other things, that the Exchange's rules 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, in general, to protect investors and the public interest. The Commission also finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 11A(a)(1)(C)(iii) of the Act, which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.³⁶ In addition, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(1) of the Act,³⁷ which requires, among other things, that the Exchange is so organized and has the capacity to be able to enforce compliance by its members and persons associated with its members with the rules of the Exchange.

The Exchange proposes to adopt new NYSE Arca Rule 5.2–E(j)(9) to permit the generic listing and trading, or trading pursuant to unlisted trading privileges, of Class ETF Shares in connection with the Multi-Class Fund Exemptive Relief granted by order under the Investment Company Act.³⁸ Under the proposal and pursuant to the Multi-Class Fund Exemptive Relief, a Multi-

³⁴ In approving this proposed rule change, as modified by Amendment No. 2, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³⁵ 15 U.S.C. 78f(b)(5).

³⁶ See 15 U.S.C. 78k–1(a)(1)(C)(iii).

³⁷ 15 U.S.C. 78f(b)(1).

³⁸ See *supra* note 17 and accompanying text.

Class Fund is permitted to issue a class of shares that are exchange-traded (*i.e.*, ETF Class) and one or more classes of shares that are not exchange-traded. In accordance with the Multi-Class Fund Exemptive Relief, the ETF Class operates as an ETF in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in the Multi-Class Fund Exemptive Relief. The Exchange also proposes conforming changes to the Exchange's definitions, corporate governance requirements under NYSE Arca Rule 5.3–E, and other provisions to accommodate the proposed listing of Class ETF Shares.

A. Consistency With Section 6(b)(5) of the Act

(1) Proposed NYSE Arca Rule 5.2–E(j)(9)

Proposed NYSE Arca Rule 5.2–E(j)(9) is reasonably designed to help prevent fraudulent and manipulative acts and practices. Proposed NYSE Arca Rule 5.2–E(j)(9) is based on NYSE Arca Rule 5.2–E(j)(8), which governs the generic listing and trading of ETF Shares on the Exchange.³⁹ Under current NYSE Arca Rule 5.2–E(j)(8), ETF Shares, which must be eligible to operate in reliance on Rule 6c–11 under the Investment Company Act and must satisfy the requirements of Rule 6c–11 under the Investment Company Act on an initial and continued listing basis, are similar to Class ETF Shares because, under the proposal, the ETF Class also is required to operate as an ETF and be in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act (except as noted in the Multi-Class Fund Exemptive Relief).⁴⁰

As stated in the ETF Shares Approval Order, a central qualification for listing under the proposed rule is ongoing compliance with Rule 6c–11 under the Investment Company Act, which requires, among other things, ETFs to prominently disclose the portfolio holdings that will form the basis for each calculation of net asset value per

share.⁴¹ Because initial and ongoing compliance with Rule 6c–11 of the Investment Company Act is a condition for listing and trading Class ETF Shares on the Exchange,⁴² proposed NYSE Arca Rule 5.2–E(j)(9) would permit the Exchange to list and trade shares of an investment company with a fully transparent portfolio,⁴³ and as the Commission previously stated for ETF Shares,⁴⁴ portfolio transparency should equally help prevent manipulation of the price of Class ETF Shares.⁴⁵ Additionally, proposed NYSE Arca Rule 5.2–E(j)(9) includes requirements relating to fire walls and procedures to prevent the use and dissemination of material, non-public information regarding the applicable Multi-Class Fund index and portfolio,⁴⁶ all such

³⁹ See ETF Shares Approval Order, *supra* note 39, 85 FR at 21487. See also ETF Rule Adopting Release, *supra* note 14, 84 FR at 57180–81.

⁴⁰ See proposed NYSE Arca Rule 5.2–E(j)(9)(e)(1) (“Class ETF Shares will be listed and traded on the Exchange provided that . . . the ETF Class is in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act of 1940, except as noted in such Multi-Class Fund Exemptive Relief”) and NYSE Arca Rule 5.2–E(j)(9)(e)(2) (“The Exchange will consider the suspension of trading in, and will commence delisting proceedings under Rule 5.5–E(m) of, Class ETF Shares . . . if the Exchange becomes aware that with respect to the Class ETF Shares . . . the ETF Class is no longer in compliance with the conditions and requirements of Rule 6c–11 under the Investment Company Act of 1940, except as noted in such Multi-Class Fund Exemptive Relief”).

⁴¹ The Commission stated that, with respect to ETF portfolio transparency, the disclosures are designed to promote an effective arbitrage mechanism and inform investors about the risks of deviation between market price and net asset value when deciding whether to invest in ETFs generally or in a particular ETF. See ETF Rule Adopting Release, *supra* note 14, 84 FR at 57166.

⁴² See ETF Shares Approval Order, *supra* note 43, 85 FR at 21487 (concluding that because initial and ongoing compliance with Rule 6c–11 of the Investment Company Act is a condition for listing and trading on the Exchange, the proposed rule would permit the listing and trading of shares of an investment company with a fully transparent portfolio, and the Commission believes that portfolio transparency should help prevent manipulation of the price of ETF Shares).

⁴³ See ETF Rule Adopting Release, *supra* note 14, 84 FR at 57169 (concluding that portfolio transparency combined with existing requirements should be sufficient to protect against certain abuses).

⁴⁴ For example, proposed Commentary .01(a)(1) to NYSE Arca Rule 5.2–E(j)(9) provides that, with respect to Class ETF Shares that are based on an index, if the underlying index is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser will erect and maintain a “fire wall” around the personnel who have access to information concerning changes and adjustments to the index, and the index will be calculated by a third party who is not a broker-dealer or fund adviser. Proposed Commentary .01(b) to NYSE Arca Rule 5.2–E(j)(9) further states that, with respect to a Multi-Class Fund that is actively managed, if the investment adviser to the Multi-Class Fund issuing Class ETF Shares is affiliated with a broker-dealer, such investment adviser will erect and maintain a “fire wall” between the investment adviser and the

requirements of which are substantively identical to those applicable to ETF Shares under NYSE Arca Rule 5.2–E(j)(8) and are designed to prevent fraudulent and manipulative acts and practices.⁴⁷ Certain of these requirements relating to such fire walls and procedures apply in addition to what is already required under the Act and the Investment Company Act and respective rules and regulations thereunder, and such requirements collectively provide additional protections against the potential misuse of material, non-public information.⁴⁸ The Commission concludes that the proposed requirements relating to such fire walls and procedures, combined with Multi-Class Fund portfolio transparency with respect to the ETF Class and the existing requirements under the Act and Investment Company Act, should help to protect against fraudulent and manipulative acts and

broker-dealer with respect to access to information concerning the composition and/or changes to such Multi-Class Fund's portfolio. Proposed Commentary .01(a)(2) to NYSE Arca Rule 5.2–E(j)(9) requires that any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the index composition, methodology, and related matters must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable index. For actively managed Multi-Class Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable portfolio. See generally Commentary .01(b) to NYSE Arca Rule 5.2–E(j)(9). Compare proposed NYSE Arca Rule 5.2–E(j)(9)(e) (encompassing the initial and continued listing requirements for Class ETF Shares) with NYSE Arca Rule 5.2–E(j)(8)(e) (encompassing the initial and continued listing requirements for ETF Shares).

⁴⁷ In adopting Rule 6c–11 under the Investment Company Act, the Commission stated that the safeguards in the existing regulatory regime adequately address “special concerns that self-indexed ETFs present, including the potential ability of an affiliated index provider to manipulate an underlying index to the benefit or detriment of a self-indexed ETF.” See ETF Rule Adopting Release, *supra* note 14, 84 FR at 57168. See also ETF Shares Approval Order, *supra* note 39, 85 FR at 21487 (concluding that the requirements of NYSE Arca Rule 5.2–E(j)(8), which includes provisions relating to fire walls and procedures to prevent the use and dissemination of material, non-public information regarding the applicable ETF index and portfolio for ETF Shares, are designed to prevent fraudulent and manipulative acts and practices).

⁴⁸ See ETF Shares Approval Order, *supra* note 39, 85 FR at 21487 (stating that the requirements for ETF Shares relating to fire walls and procedures, which are substantively identical to NYSE Arca's rules governing the listing and trading of index-based and actively managed ETFs, apply in addition to what is already required under the Act and the Investment Company Act and respective rules and regulations thereunder, and that such requirements collectively provide additional protections against the potential misuse of material, non-public information).

³⁹ See NYSE Arca Rule 5.2–E(j)(8). See also *supra* note 15 and accompanying text; See Securities Exchange Act No. 88625 (April 13, 2020) 85 FR 21479 (April 17, 2020) (SR–NYSEArca–2019–81) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, to Adopt NYSE Arca Rule 5.2–E(j)(8) Governing the Listing and Trading of ETF Shares) (“ETF Shares Approval Order”).

⁴⁰ The Exchange represents that the proposed Class ETF Shares generic listing rules apply only to the class of shares (ETF Class) that are exchange-traded.

practices under Section 6(b)(5) of the Act.⁴⁹

Proposed NYSE Arca Rule 5.2–E(j)(9)(g) requires that the Exchange implement and maintain written surveillance procedures for Class ETF Shares. The Exchange represents that it will utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to ETF Shares, among other product types, to monitor trading in Class ETF Shares, and further represents that its surveillance procedures are adequate to (a) properly monitor the trading of the Class ETF Shares during all trading sessions and (b) deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange also represents that the Exchange, or FINRA on behalf of the Exchange, will communicate as needed regarding trading in Class ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange also may obtain information regarding trading in Class ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by the Multi-Class Fund for the Class ETF Shares reported to TRACE. FINRA also can access data obtained from the EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in Class ETF Shares, to the extent that the Multi-Class Fund for the Class ETF Shares holds municipal securities. The Exchange states that NYSE Arca Rule 5.2–E(j)(9)(e) requires any issuer to provide the Exchange with prompt notification after it becomes aware that (i) the Multi-Class Fund is no longer eligible to operate an ETF Class as an exchange-traded fund pursuant to, or otherwise no longer complies with, the terms and conditions of, the Multi-Class Fund Exemptive Relief, (ii) the ETF Class is no longer compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act,

except as noted in such Multi-Class Fund Exemptive Relief, or (iii) the ETF Class or the Multi-Class Fund no longer satisfies the requirements of NYSE Arca Rule 5.2–E(j)(9), as applicable, on an initial and continuing basis.⁵⁰ The Exchange further represents that it will obtain a representation from the issuer of Class ETF Shares stating that the requirements of Rule 6c–11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied and that the issuer will notify the Exchange of any failure to do so.

Consistent with the requirement of Section 6(b)(5) of the Act⁵¹ that the Exchange's rules be designed to remove impediments to and perfect the mechanism of a free and open market, the Exchange's rules regarding trading halts will help to ensure the maintenance of fair and orderly markets for Class ETF Shares. Specifically, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in Class ETF Shares. The Exchange states that trading in Class ETF Shares may be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached, because of other market conditions, or for reasons that, in the view of the Exchange, make trading in the Class ETF Shares inadvisable. According to the Exchange, the reasons to halt trading may include: (1) the extent to which certain information about the Class ETF Shares that is required to be disclosed pursuant to Rule 6c–11 under the Investment Company Act is not being made available;⁵² (2) if an interruption to the dissemination to the value of the index or reference asset on which the Class ETF Shares is based persists past the trading day in which it occurred or is no longer calculated or available; (3) trading in the securities comprising the underlying index or portfolio has been halted in the primary market(s); or (4) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. As the Exchange

further represents in the proposal, if the Exchange becomes aware that the net asset value or the daily portfolio disclosure with respect to the Class ETF Shares is not disseminated to all market participants at the same time, it will halt trading in the Class ETF Shares until such time as the net asset value or the daily portfolio disclosure is available to all market participants.⁵³ The Exchange represents that it may suspend trading in and commence delisting proceedings for Class ETF Shares where such securities are not in compliance with the applicable listing standards or where the Exchange believes that further dealings on the Exchange are inadvisable.⁵⁴

The Commission also finds that, consistent with Section 11A(a)(1)(C)(iii) of the Act,⁵⁵ the proposed rule change, as modified by Amendment No. 2, is reasonably designed to promote fair disclosure of information that may be necessary to price the Class ETF Shares appropriately, to prevent trading when a reasonable degree of transparency cannot be assured, to safeguard material non-public information relating to the Class ETF Shares, and to ensure fair and orderly markets for Class ETF Shares.

(2) Other Related Proposed Rule Changes

The Exchange also proposes changes to accommodate Class ETF Shares in other Exchange rules. First, the Exchange proposes to add Class ETF Shares to the definition of “Derivative Securities Product and UTP Derivative Securities Product” in NYSE Arca Rule 1.1. Second, the Exchange proposes to amend NYSE Arca Rule 5.3–E to exempt Class ETF Shares from the requirements of Rule 5.3–E(d)(9) in connection with the acquisition of the stock or assets of an affiliated registered investment company in a transaction that complies with Rule 17a–8 under the Investment Company Act and does not otherwise require shareholder approval under the Investment Company Act⁵⁶ and the rules thereunder or any other Exchange rule. In addition, the Exchange proposes to add proposed Rule 5.2–E(j)(9) to the last paragraph of Rule 5.3–E, which defines derivative and special purpose securities for purposes of Rule 5.3–E.⁵⁷

⁴⁹ See *id.*

⁵⁰ See *supra* note 24 and accompanying text.

⁵¹ See *supra* note 36 and accompanying text.

⁵² The Exchange also proposes non-substantive, technical changes to delete two extraneous words in this rule. See *supra* note 19.

⁵³ The Exchange states that these proposed changes would subject Class ETF Shares to the same corporate governance requirements as other open-end management investment companies listed on the Exchange. See *supra* note 20 and accompanying text.

⁴⁹ See *id.* (“Therefore, the Commission concludes that the proposed requirements relating to such fire walls and procedures, combined with ETF portfolio transparency and the existing requirements under the Act and [Investment Company Act], should help to protect against fraudulent and manipulative acts and practices under Section 6(b)(5) of the Act.”).

⁵⁰ See *supra* note 25 and accompanying text. See also NYSE Arca Rule 5.2–E(b) (requiring, among other things, that “[a]n issuer with securities listed under Rule 5.2–E . . . must provide the Exchange with prompt notification after the issuer becomes aware of any noncompliance by the issuer with the applicable continued listing requirements . . .”).

⁵¹ 15 U.S.C. 78f(b)(5).

⁵² The Exchange will obtain a representation from the issuer of Class ETF Shares that the net asset value per share will be calculated daily and made available to all market participants at the same time, and the requirements pertaining to the Multi-Class Fund Exemptive Relief and Rule 6c–11 under the Investment Company Act in proposed NYSE Arca Rule 5.2–E(j)(9) will be satisfied. See *supra* note 27 and accompanying text.

These proposed changes incorporate proposed NYSE Arca Rule 5.2–E(j)(9) into the existing framework of the Exchange's rules, and therefore the Commission finds that such changes are consistent with Section 6(b)(5) of the Act.

B. Consistency With Section 6(b)(1) of the Act

The Commission also finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(1) of the Act,⁵⁸ which requires, among other things, that the Exchange is so organized and has the capacity to be able to enforce compliance by its members and persons associated with its members with the rules of the Exchange. The Exchange represents that, consistent with Section 6(b)(1) of the Act,⁵⁹ it has the capacity to enforce proposed NYSE Arca Rule 5.2–E(j)(9) and that it will perform ongoing surveillance of Class ETF Shares listed on the Exchange to ensure that: (1) the Multi-Class Fund is and continues to be eligible to operate an ETF Class as an ETF pursuant to, and is otherwise in compliance with the terms and conditions of, the Multi-Class Fund Exemptive Relief; (2) the ETF Class continues to be compliant with the conditions and requirements of Rule 6c–11 under the Investment Company Act, except as noted in such Multi-Class Fund Exemptive Relief; and (3) the ETF Class and the Multi-Class Fund each satisfies the requirements of proposed NYSE Arca Rule 5.2–E(j)(9), as applicable, on an initial and continued listing basis. In addition, the Exchange represents that it will review the website of the Class ETF Shares listed on the Exchange to ensure that the requirements of Rule 6c–11 under the Investment Company Act are being met and will obtain a representation from the issuer of the Class ETF Shares that the requirements of Rule 6c–11 and the applicable exemptive relief under the Investment Company Act will be continuously satisfied, and that the issuer will notify the Exchange of any failure to do so. The Exchange also represents that it will comply with all the requirements of Rule 19b–4(e) to specifically note that such Class ETF Shares are being listed on the Exchange pursuant to NYSE Arca Rule 5.2–E(j)(9).⁶⁰

The Exchange states that it will employ numerous intraday alerts to notify Exchange personnel of trading activity throughout the day that is potentially indicative of certain disclosures not being made accurately or the presence of other unusual conditions or circumstances that could be detrimental to the maintenance of a fair and orderly market. The Exchange also states that proposed NYSE Arca Rule 5.2–E(j)(9) requires any issuer to provide the Exchange with prompt notification after it becomes aware of any non-compliance with proposed NYSE Arca Rule 5.2–E(j)(9),⁶¹ which would include any failure of the issuer to comply with Rule 6c–11 under the Investment Company Act or with the terms and conditions of the Multi-Class Fund Exemptive Relief.⁶² Further, proposed NYSE Arca Rule 5.2–E(j)(9)(e)(2)(C) requires that the Exchange consider the suspension of trading in, and commence delisting proceedings for, Class ETF Shares if, following the initial 12-month period after commencement of trading on the Exchange, there are fewer than 50 beneficial holders of the Class ETF Shares.⁶³ Finally, the Exchange deems Class ETF Shares to be equity securities and represents, therefore, that such Class ETF Shares would be subject to the full panoply of Exchange rules and procedures that currently govern the trading of equity securities on the Exchange.⁶⁴ The Exchange states that Class ETF Shares will be subject to rules governing Exchange member disclosure obligations in connection with equities trading, and that Rule 6c–11 under the Investment Company Act does not change the applicability of these Exchange rules with respect to these securities.⁶⁵

using the most recent versions of the XML schema and the associated PDF renderer as published on the Commission's website: (A) type of issuer; (B) class; (C) name of underlying instrument; (D) if the underlying instrument is an index, whether it is broad-based or narrow-based; (E) ticker symbol(s); (F) market(s) upon which securities composing the underlying instrument trade; (G) settlement methodology; and (H) position limits (if applicable). See 17 CFR 240.19b–4(e)(2)(ii). See also *supra* notes 10 and 18 and respective accompanying text.

⁶¹ See NYSE Arca Rule 5.2–E(b) (requiring, among other things, that “[a]n issuer with securities listed under Rule 5.2–E . . . must provide the Exchange with prompt notification after the issuer becomes aware of any noncompliance by the issuer with the applicable continued listing requirements. . . .”).

⁶² See *supra* note 50 and accompanying text.

⁶³ See proposed NYSE Arca Rule 5.2–E(j)(9)(e)(2)(C).

⁶⁴ See *supra* note 28 and accompanying text.

⁶⁵ With respect to trading in Class ETF Shares, the Exchange represents that all ETP Holder obligations relating to product description and prospectus delivery requirements will continue to apply in accordance with the Exchange's rules and federal

This approval order is based on all of the Exchange's representations and descriptions in the proposed rule change, including those set forth above and in Amendment No. 2, which the Commission has carefully evaluated as discussed above. For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Sections 6(b)(1) and 6(b)(5) of the Act⁶⁶ and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendment No. 2 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether the proposed rule change, as modified by Amendment No. 2, 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–2025–39 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–2025–39. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2025–39

securities laws, and the Exchange will continue to monitor ETP Holders for compliance with such requirements, which are not changing as a result of the Multi-Class Fund Exemptive Relief order issued under the Investment Company Act. See *supra* note 28 and accompanying text.

⁶⁶ 15 U.S.C. 78f(b)(1) and 15 U.S.C. 78f(b)(5), respectively.

⁵⁸ 15 U.S.C. 78f(b)(1).

⁵⁹ *Id.*

⁶⁰ Rule 19b–4(e) requires an SRO seeking to rely on Rule 19b–4(e) to post on its publicly available internet website within five business days after commencement of trading a new derivative securities product the following information relating to the new derivative securities product,

and should be submitted on or before December 19, 2025.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 2

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 2, prior to the 30th day after the date of publication of Amendment No. 2 in the **Federal Register**. Amendment No. 2 reflects the Commission's grant of the Multi-Class Fund Exemptive Relief and provides additional clarity with respect to the application of the Exchange's proposed listing standards and the requirements of the Multi-Class Fund Exemptive Relief. Amendment No. 2 also makes certain additional corrections that are minor and technical in nature. In addition, the proposal, as modified by Amendment No. 1, has been subject to public comment and no comments have been received.

The Commission finds that Amendment No. 2 to the proposed rule change raises no novel regulatory issues that have not previously been subject to comment, and is reasonably designed, among other things, to prevent fraudulent and manipulative acts and practices, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest. The Commission also finds that Amendment No. 2 to the proposed rule change is consistent with Section 11A(a)(1)(C)(iii) of the Act.⁶⁷ Accordingly, pursuant to Section 19(b)(2) of the Act,⁶⁸ the Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁶⁹ that the proposed rule change (SR-NYSEARCA-2025-39), as modified by Amendment No. 2, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-21405 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0444]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 10b-10

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("SEC" or "Commission") is soliciting comments on the proposed collection of information provided for in Rule 10b-10 (17 CFR 240.10b-10) under the Securities and 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 10b-10 requires broker-dealers to disclose specified information to customers regarding their securities transactions. The information required by the rule includes the date and time of the transaction, the identity and number of shares bought or sold, and whether the broker-dealer acts as agent for the customer or as principal for its own account. In addition, depending on whether the broker-dealer acts as agent for the customer or as principal for its own account, the rule requires the disclosure of commissions and, under specified circumstances, mark-up and mark-down information. For transactions in debt securities (other than U.S. savings bonds and municipal securities) the rule requires the disclosure of redemption and yield information. For transactions in securities futures products in a futures account, the rule permits the disclosure of alternative information. This alternative information includes: the date the transaction was executed; the identity and number of shares bought or sold; the price, the delivery month, and the exchange on which the transaction was executed; the source and amount of any remuneration received or to be received by the broker-dealer in connection with the transaction; whether the broker receives payment for order flow for such transactions; and the fact that other specified information, including whether the broker-dealer is acting as agent or principal, will be available upon written request. Rule 10b-10 also requires broker-dealers to

inform their customers if they are not members of the Securities Investor Protection Corporation ("SIPC").

The confirmation has long been a customary document in the securities industry, and it serves several functions, which include: broker-dealers use it as a billing statement; it serves as a customer invoice; it informs customers of the details of transactions and facilitates their checking for errors or misunderstandings; it provides information that helps investors evaluate the cost and quality of services provided by broker-dealers; it discloses conflicts of interest that may arise between investors and broker-dealers; and it safeguards against fraud by helping customers detect problems with transactions.

Rule 10b-10 potentially applies to all the approximately 3,292 broker-dealers that are registered with the Commission and that effect transactions for or with customers. Based on information provided by registered broker-dealers to the Commission in annual Form X-17a-5 Schedule I FOCUS Reports filed from January 1, 2022 to December 31, 2024, the Commission staff estimates that on average, registered broker-dealers process approximately 36,202,574,610 order tickets per year for transactions for or with customers. Each order ticket representing a transaction effected for or with a customer generally results in one confirmation. Therefore, the Commission staff estimates that approximately 36,202,574,610 confirmations are sent to customers annually. Based on information provided by industry participants, Commission staff estimates that it takes approximately 30 seconds to generate and send a confirmation. As a result, the Commission staff estimates that the annual burden to brokers-dealers to comply with the confirmation delivery requirements of Rule 10b-10 would be approximately 301,688,122 hours (36,202,574,610 confirmation × 0.5 minutes/confirmation × 1 hour/60 minutes).

Based on informal discussions with securities industry representatives, as well as representations made in requests for exemptive and no-action letters, Commission staff estimates that broker-dealers use electronic confirmations as their sole confirmations for approximately 35 percent of transactions. Commission staff estimates that broker-dealers continue to send paper confirmations for the remaining 65 percent of transactions. Accordingly, approximately 23,531,673,497 paper confirmations are mailed to customers each year (36,202,574,610 × 0.65) and 12,670,901,114 wholly electronic

⁶⁷ See *supra* note 36 and accompanying text.

⁶⁸ 15 U.S.C. 78s(b)(2).

⁶⁹ *Id.*

⁷⁰ 17 CFR 200.30-3(a)(12).

confirmations are sent each year (36,202,574,610 × 0.35).

According to information provided by industry participants, the Commission staff estimates that the average cost for a paper confirmation is 85 cents and the average cost for a wholly electronic confirmation is 40 cents. Accordingly, the Commission staff estimates that the total annual cost associated with generating and mailing paper confirmations is approximately \$20,001,922,473 (23,531,673,497 paper confirmations × \$0.85 per confirmation) and the total annual cost associated with generating and sending wholly electronic confirmations is approximately \$5,068,360,446 (12,670,901,114 electronic confirmations × \$0.40 per confirmation). Accordingly, Commission staff estimates that the total annual cost associated with generating and delivering to investors the information required under Rule 10b–10 is approximately \$25,070,282,919 (\$20,001,922,473 + \$5,068,360,446).

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by January 27, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: November 24, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–21391 Filed 11–26–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104244; File No. SR–NYSENAT–2025–24]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Rebates

November 24, 2025.

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 30, 2025, NYSE National, Inc. (“NYSE National” or the “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 proposes to amend its Schedule of Fees and Rebates (“Fee Schedule”) to (1) eliminate the rebate currently provided for non-tiered orders removing liquidity in securities priced at or above \$1.00 that do not execute at a price better than the contra-side NBBO; and (2) add new Removing Tier 4. The proposed 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 Exchange proposes to amend its Schedule of Fees and Rebates (“Fee Schedule”) to (1) eliminate the rebate currently provided for non-tiered orders removing liquidity in securities priced at or above \$1.00 that do not execute at a price better than the contra-side NBBO; and (2) add Removing Tier 4.

The proposed changes respond to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing and liquidity-removing orders by offering further incentives for ETP Holders to send additional removing liquidity to the Exchange.

The Exchange proposes to implement the rule change on October 1, 2025.

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, 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.”³

As the Commission itself has recognized, the market for trading services in NMS stocks has become “more fragmented and competitive.”⁴ Indeed, cash equity trading is currently dispersed across 16 exchanges,⁵ numerous alternative trading systems,⁶ and numerous broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no

³ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (“Regulation NMS”).

⁴ See Securities Exchange Act Release No. 51808, 84FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (“Transaction Fee Pilot”).

⁵ See Cboe Global Markets, U.S. Equities Market Volume Summary, available at http://markets.cboe.com/us/equities/market_share/. See generally <https://www.sec.gov/fast-answers/divisionsmarketregmrexchangeshtml.html>.

⁶ See FINRA ATS Transparency Data, available at <https://otctransparency.finra.org/otctransparency/AtsIssueData>. A list of alternative trading systems registered with the Commission is available at <https://www.sec.gov/foia/docs/atlist.htm>.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

single exchange has more than 20% of the market.⁷ Therefore, no exchange possesses significant pricing power in the execution of cash equity order flow. More specifically, the Exchange's share of executed volume of equity trades in Tapes A, B and C securities is less than 2%.⁸

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain products, in response to fee changes. While it is not possible to know a firm's reason for moving order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange trading venues to which a firm routes order flow. These fees can vary from month to month, and not all are publicly available. With respect to non-marketable order flow that would provide liquidity on an exchange, ETP Holders can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange utilizes a "taker-maker" or inverted fee model to attract orders that provide liquidity at the most competitive prices. Under the taker-maker model, offering rebates for taking (or removing) liquidity increases the likelihood that market participants will send orders to the Exchange to trade with liquidity providers' orders. This increased taker order flow provides an incentive for market participants to send orders that provide liquidity. The Exchange generally charges fees for order flow that provides liquidity. These fees are reasonable due to the additional marketable interest (in part attracted by the Exchange's rebate to remove liquidity) with which those order flow providers can trade.

Proposed Rule Change

To respond to this competitive environment, the Exchange proposes the following changes to its Fee Schedule designed to provide order flow providers with additional incentives to route order flow to the Exchange. As described above, ETP Holders have a choice of where to send their order flow.

First, the Exchange proposes to remove its current rebate of \$0.0016 per share for non-tiered orders removing liquidity in securities priced at or above \$1.00 that do not execute at a price better than the contra-side NBBO. Under the proposal, such orders would receive no rebate. The Exchange already provides no rebate for removing liquidity that executes at a price better than the contra-side NBBO, and that would remain unchanged.

The Exchange believes that eliminating the rebate for non-tiered orders described above is competitive and would still incentivize ETP Holders to send liquidity-removing orders to the Exchange. Even with the removal of the rebate, the Exchange's charges for non-tiered orders removing liquidity in securities priced at or above \$1.00 would still be more advantageous to ETP Holders than comparable rates at at least one of the Exchange's competitors.⁹

Second, in conjunction with removing the rebate for non-tiered orders described above, the Exchange also proposes to introduce new Removing Tier 4. Under the proposed Removing Tier 4, the Exchange would provide a rebate of \$0.0010 per share to ETP Holders that remove liquidity for orders that do not execute at a price better than the contra-side NBBO from the Exchange in securities with a per share price of \$1.00 or more and that have at least 50,000 Adding ADV.

The Exchange believes that this change will incentivize more ETP Holders to route liquidity-adding order flow to the Exchange to meet the tier requirements for Removing Tier 4. For ETP Holders that cannot meet the higher requirements of current Removing Tier 3, the Exchange believes that the addition of proposed Removing Tier 4 would encourage additional removing order flow to the Exchange by providing a \$0.0010 per share rebate for orders that do not execute at a price better than the contra-side NBBO for ETP Holders that meet the 50,000 Adding ADV requirement. The Exchange believes that the increased order flow that may result from these proposed changes would in turn support the quality of price discovery on the Exchange and provide additional price improvement opportunities for incoming orders.

As noted, the Exchange operates in a competitive environment. The Exchange does not know how much order flow ETP Holders choose to route to other

exchanges or to off-exchange venues. Based on the profile of firms generally, the Exchange believes that with the proposed change, additional ETP Holders could choose to direct order flow to the Exchange. Without having a view of ETP Holders' activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any additional ETP Holders directing orders to the Exchange.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."¹² While Regulation NMS has enhanced competition, it has also fostered a "fragmented" market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that "such competition can lead to the fragmentation of order flow in that stock."¹³

In light of the competitive environment in which the Exchange

⁷ See Cboe Global Markets U.S. Equities Market Volume Summary, available at http://markets.cboe.com/us/equities/market_share/.

⁸ See *id.*

⁹ See, e.g., Nasdaq BX Exchange Fee Schedule, available at https://www.nasdaqtrader.com/trader.aspx?id=bx_pricing (providing \$0.0007 standard fee for removing displayed liquidity).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) & (5).

¹² See Regulation NMS, *supra* note 4, at 37499.

¹³ See Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7-02-10) (Concept Release on Equity Market Structure).

currently operates, the proposed rule change is a reasonable attempt to incentivize member organizations to direct order flow to the Exchange and provide additional liquidity in order to qualify for favorable pricing and rebates, thereby contributing to depth and market quality on the Exchange.

The Proposed Change Is Reasonable

The Exchange believes that the proposal represents a reasonable attempt to attract additional order flow to the Exchange while realigning the Exchange's fees with those charged by other markets. The current rebate of \$0.0016 for non-tiered orders removing liquidity in securities priced at or above \$1.00 that do not execute at a price better than the contra-side NBBO has not operated in the way the Exchange anticipated, in that it did not drive significant volume from ETP Holders that do not qualify for Removing Tiers. As such, the Exchange proposes to remove it. Even with the removal of the rebate, however, the Exchange's pricing will remain competitive when compared to the fees charged by at least one other market for non-tiered orders removing liquidity.¹⁴

Additionally, the Exchange believes that proposed Removing Tier 4 is reasonable. For ETP Holders that cannot meet the higher requirements of current Removing Tier 3, the Exchange believes that the addition of proposed Removing Tier 4 would encourage additional removing order flow to the Exchange by providing a \$0.0010 per share rebate for ETP Holders that meet the 50,000 Adding ADV requirement.

The Exchange believes that the proposal represents a reasonable effort to promote price discovery and enhanced order execution opportunities for ETP Holders. All ETP Holders would benefit from the greater amounts of liquidity on the Exchange, which would represent a wider range of execution opportunities.

The Proposal Is an Equitable Allocation of Fees and Rebates

The Exchange believes the proposed rule change equitably allocates its fees among its market participants. The proposed change would continue to encourage ETP Holders to both submit removing liquidity to the Exchange and execute orders on the Exchange, thereby contributing to robust levels of liquidity, to the benefit of all market participants.

The Exchange believes that eliminating the rebate of \$0.0016 for non-tiered orders removing liquidity in securities priced at or above \$1.00 that

do not execute at a price better than the contra-side NBBO and adding Removing Tier 4 is an equitable allocation of fees and credits. Even with the removal of the rebate for non-tiered orders removing liquidity, the Exchange's fees will remain competitive when compared to the fees charged by at least one other market for non-tiered orders removing liquidity.¹⁵ To the extent that the proposed change attracts order flow to the Exchange, this order flow would make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would continue to improve market quality for all market participants on the Exchange and, as a consequence, continue to attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

The Exchange further believes that the proposal constitutes an equitable allocation of fees and credits because all similarly situated ETP Holders and other market participants would be eligible for the same general and tiered rebates for removing liquidity. Moreover, the proposed change is equitable because the proposed rebates would apply equally to all similarly situated ETP Holders. The proposal neither targets nor will it have a disparate impact on any particular category of market participant.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, ETP Holders are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

Moreover, the proposal neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal does not permit unfair discrimination because the proposal would be applied to all similarly situated ETP Holders, and all ETP Holders would be subject to the same change to the rebate for non-tiered orders and the addition of Removing Tier 4. Accordingly, no ETP Holder already operating on the Exchange would be disadvantaged by the proposed allocation of fees and credits.

The Exchange further believes that the proposed change would not permit unfair discrimination among ETP Holders because the non-tiered and tiered rates are available equally to all ETP Holders. As described above, in

today's competitive marketplace, order flow providers have a choice of where to direct order flow, and the Exchange believes there are additional ETP Holders that could qualify if they chose to direct their order flow to the Exchange.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹⁶ the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity and order flow to a public exchange, thereby enhancing order execution opportunities for ETP Holders. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."¹⁷

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange. As described above, the Exchange believes that the proposed change would continue to incentivize market participants to direct liquidity-removing orders to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages ETP Holders to send orders, thereby contributing to robust levels of liquidity. The proposed changes would be available to all similarly-situated market participants, and thus, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its

¹⁴ See *supra* note 10.

¹⁵ See *supra* note 10.

¹⁶ 15 U.S.C. 78f(b)(8).

¹⁷ Regulation NMS, 70 FR at 37498–99.

fees and rebates to remain competitive with other exchanges and off-exchange venues. Because competitors are free to modify their own fees and rebates in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

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

Pursuant to Section 19(b)(3)(A)(ii) of the Act,¹⁸ and Rule 19b-4(f)(2) thereunder¹⁹ the Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing. 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-NYSENAT-2025-24 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-NYSENAT-2025-24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSENAT-2025-24 and should be submitted on or before December 19, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Stephanie J. Fouse,
Assistant Secretary.

[FR Doc. 2025-21398 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0766]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 17a-14 and Form CRS

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("SEC" or "Commission") is soliciting comments on the proposed collection of information provided for in Rule 17a-14 (17 CFR 240.17a-14) and Form CRS (17 CFR 249.640), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17a-14 and Form CRS require a broker-dealer that offers services to retail investors to prepare and file with the Commission through WebCRD, post

to the broker-dealer's website (if it has one), and deliver to retail investors a relationship summary. The relationship summary can assist retail investors in making an informed choice about whether to hire or retain a broker-dealer, as well as what types of accounts and services are appropriate for their needs.

The information that must be collected pursuant to Rule 17a-14 and Form CRS is necessary to provide broker-dealer retail customers, prospective retail customers, and the Commission with information about the relationships and services the firm offers to retail investors, fees and costs that the retail investor will pay, specific conflicts of interest and standards of conduct, legal or disciplinary history, and how to obtain additional information about the firm. The Commission uses the information to manage its regulatory and examination programs. Retail investors can use the information required in the relationship summary to determine whether to hire or retain a broker-dealer, as well as what types of accounts and services are appropriate for their needs. The information will therefore help establish a framework that protects investors and promotes efficiency, competition, and capital formation.

The aggregate annual hour burden for all respondents to comply with the information collection requirements of Rule 17a-14 and Form CRS is estimated to be approximately 6,426,099 hours per year. Under Rule 17a-14 and Form CRS, respondents will also incur cost burdens. The aggregate annual cost burden for all respondents is estimated to be approximately \$142,554 per year.

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comment on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data

¹⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁹ 17 CFR 240.19b-4.

²⁰ 17 CFR 200.30-3(a)(12).

Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by January 27, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: November 24, 2025.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025–21393 Filed 11–26–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104242; File No. SR–CboeBZX–2025–142]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend Rule 11.9(d) To Permit an Intermarket Sweep Order Containing a Time-in-Force Other Than IOC To Be Entered as a Non-Displayed Order

November 24, 2025.

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 November 13, 2025, Cboe BZX Exchange, Inc. (the “Exchange” or “BZX”) 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

Cboe BZX Exchange, Inc. (the “Exchange” or “BZX”) proposes to amend Rule 11.9(d) to permit an Intermarket Sweep Order containing a time-in-force other than IOC to be entered as a Non-Displayed Order. The Exchange also proposes to amend Rule 11.9(c)(11) and Rule 11.13(a)(4)(C)–(D) in order to describe the behavior of Non-Displayed Orders. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission’s website (<https://www.sec.gov/rules/sro.shtml>), the Exchange’s website (<https://www.cboe.com/us/equities/>

[regulation/rule_filings/bzx/](#)), and 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 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

As part of its suite of product offerings, BZX currently offers Users the ability to enter Intermarket Sweep Orders (“ISOs”), which are limit orders for an NMS stock that meet the following requirements: (i) when routed to a trading center, the limit order is identified as an ISO; (ii) simultaneously with the routing of the limit order identified as an ISO, one or more additional limit orders, as necessary, are routed to execute against the full displayed size of any protected bid, in the case of a limit order to sell, or the full displayed size of any protected offer, in the case of a limit order to buy, for the NMS stock with a price that is superior to the limit price of the limit order as identified as an ISO (and these additional routed orders also must be marked as ISOs).³ Currently, the Exchange does not specify that ISOs may be entered as Non-Displayed Orders.⁴ Based on User⁵ feedback, the Exchange proposes to amend Rule 11.9(d) to permit ISOs entered with a time-in-force other than Immediate or Cancel (“IOC”)⁶ to be entered as Non-

Displayed Orders (“Non-Displayed ISOs”). In conjunction with the proposed amendment to Rule 11.9(d), the Exchange also proposes to amend Rule 11.9(c)(11) and Rule 11.13(a)(4)(C)–(D) in order to more accurately describe the price at which a Non-Displayed Order posts to the BZX Book⁷ and at what price a Non-Displayed Order may execute in certain situations.

Intermarket Sweep Orders

The Exchange currently permits Users to submit ISOs pursuant to Rule 11.9(d). In order to be eligible for treatment as an ISO, the limit order must be marked ISO and the User entering the order must simultaneously route one or more additional limit orders marked “ISO,” as necessary, to away markets to execute against the full displayed size of any Protected Quotation⁸ for the security with a price that is superior to the limit price of the ISO entered in the System.^{9,10} Such orders, if they meet the requirements of the foregoing sentence, may be executed at one or multiple price levels in the system without regard to Protected Quotations at away markets consistent with Regulation NMS (*i.e.*, may trade through such quotations).¹¹ The Exchange relies on the marking of an order as an ISO order when handling such order, and thus, it is the entering Member’s responsibility, not the Exchange’s responsibility, to comply with the requirements of Regulation NMS relation to ISOs.¹² ISOs are not eligible for routing pursuant to Rule 11.13(b).¹³

The Exchange now proposes to add language to Rule 11.9(d) that states that an ISO may be entered as a displayed order or as a Non-Displayed Order (a “Non-Displayed ISO”). In addition, the Exchange proposes to introduce Rule 11.9(d)(1) that permits a Non-Displayed ISO entered with a time-in-force other than IOC to be accepted at a price that locks a Protected Quotation because the non-displayed nature of the ISO allows it to lock a Protected Quotation under

³ See Regulation NMS Rule 600(a)(47).

⁴ See Exchange Rule 11.9(c)(11). A “Non-Displayed Order” is a market or limit order that is not displayed on the Exchange.

⁵ See Exchange Rule 1.5(cc). The term “User” shall mean any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3.

⁶ See Rule 11.9(b)(1). An Immediate-or-Cancel Order is a limit order that is to be executed in whole or in part as soon as such order is received. The portion not executed immediately on the Exchange or another trading center is treated as cancelled and is not posted to the BZX Book. IOC limit orders that are not designated as “BZX Only” and that cannot be executed in accordance with Rule 11.13(a)(4) on the System when reaching the Exchange will be eligible for routing away pursuant to Rule 11.13(b).

⁷ See Exchange Rule 1.5(e). The term “BZX Book” shall mean the System’s electronic file of orders.

⁸ See Rule 1.5(u). The term “Protected Quotation” shall mean a quotation that is a Protected Bid or Protected Offer.

⁹ See Exchange Rule 11.9(d).

¹⁰ See Exchange Rule 1.5(aa). The term “System” shall mean the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.

¹¹ *Supra* note 9.

¹² *Id.*

¹³ *Id.*

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

Regulation NMS.¹⁴ Further, the Exchange proposes to introduce Rule 11.9(d)(2) which provides that a Non-Displayed ISO entered with a time-in-force other than IOC will be accepted at a price that trades through a Protected Quotation provided that a Member simultaneously routes one or more additional limit orders marked "ISO," as necessary, to execute against the full, displayed size of any Protected Quotations in the security with a price that is superior to the limit price of the Non-Displayed ISO entered in the System. A Non-Displayed ISO will be permitted to execute through a Protected Quotation for up to one second following receipt of the order by the Exchange, subject to certain limitations.

The Exchange will also introduce rules to describe the behavior of a Non-Displayed ISO during the one second period in which the Exchange proposes to permit the Non-Displayed ISO to cross a Protected Quotation. Pursuant to proposed Rule 11.9(d)(2)(i), in the event that the Protected Quotation is unchanged after one second, the System will slide the Non-Displayed ISO pursuant to Rule 11.9(g)(4) or cancel the Non-Displayed ISO, based on User instruction. Proposed Rule 11.9(d)(2)(ii) provides that the System will immediately slide the Non-Displayed ISO pursuant to Rule 11.9(g)(4) or cancel the Non-Displayed ISO, based on User instruction, if the Protected Quotation bid becomes higher (for sell orders) or offer becomes lower (for buy orders) before the one second time period expires. The Non-Displayed ISO will remain posted at the crossing price for the entirety of the one second time period if the Protected Quotation moved lower (for sell orders) or offer moves higher (for buy orders) before the one second time period expires, pursuant to proposed Rule 11.9(d)(2)(iii). The Exchange has provided the following examples in order to illustrate the behavior of a Non-Displayed ISO with a time-in-force other than IOC that is crossing a Protected Quotation.

Example 1

The System will slide a Non-Displayed ISO pursuant to Rule 11.9(g)(4) or cancel a Non-Displayed ISO, based on User instruction, if the Protected Quotation is unchanged after one second.

NBBO: 10.00 x 10.05.

Order 1: Buy 100 at 10.06—Non-Displayed, ISO, price slide, time-in-force Day. Timestamp 12:00:00:000.

¹⁴ See proposed Rule 11.9(d)(1). See also, Nasdaq Equity 4, Rule 4702(b)(3)(C).

Order 1 is posted to the BZX Book at a ranked price of 10.06.

NBBO: 10.00 x 10.05. Timestamp: 12:00:01:000.

RESULT: Under proposed Rule 11.9(d)(2)(i), Order 1 is slid to a ranked price of 10.05 pursuant to Rule 11.9(g)(4) based on User instruction because the NBBO did not update before the one second time period expired. If, alternatively, the User had elected to have its order cancelled rather than electing price slide, Order 1 would have been cancelled at the expiration of the one second time period.

Example 2

The System will slide a Non-Displayed ISO pursuant to Rule 11.9(g)(4) or cancel a Non-Displayed ISO, based on User instruction, if the Protected Quotation bid becomes higher (for sell orders) or offer becomes lower (for buy orders) before the one second time period expires.

NBBO: 10.00 x 10.05.

Order 1: Buy 100 at 10.08—Non-Displayed, ISO, price slide, time-in-force Day. Timestamp 12:00:00:000. Order 1 is posted to the BZX Book at a ranked price of 10.08.

NBBO: 10.01 x 10.07. Timestamp: 12:00:00:100.

Order 1 remains posted to the BZX Book at a ranked price of 10.08.

NBBO: 10.01 x 10.05. Timestamp: 12:00:00:101.

RESULT: Under proposed Rule 11.9(d)(2)(ii), Order 1 is slid to a ranked price of 10.05 pursuant to Rule 11.9(g)(4) based on User instruction because the Protected Quotation offer moved lower (from 10.07 to 10.05) before the one second time period expired. Order 1 did not slide when the Protected Quotation offer moved higher (from 10.05 to 10.07). If, alternatively, the User had elected to have its order cancelled rather than electing price slide, Order 1 would have been cancelled immediately following the Protected Quotation offer's movement from 10.07 to 10.05.

Example 3

The System will slide a Non-Displayed ISO pursuant to Rule 11.9(g)(4) or cancel a Non-Displayed ISO, based on User instruction, if the Protected Quotation bid becomes higher (for sell orders) or offer becomes lower (for buy orders) before the one second time period expires.

NBBO: 10.00 x 10.05.

Order 1: Buy 100 at 10.06—Non-Displayed, ISO, price slide, time-in-force Day. Timestamp 12:00:00:000. Order 1 is posted to the BZX Book at a ranked price of 10.06.

NBBO: 10.01 x 10.07. Timestamp: 12:00:00:100.

Order 1 remains posted to the BZX Book at a ranked price of 10.06.

NBBO: 10.01 x 10.05. Timestamp: 12:00:00:101.

RESULT: Under proposed Rule 11.9(d)(2)(ii), Order 1 is slid to a ranked price of 10.05 pursuant to Rule 11.9(g)(4) based on User instruction because the Protected Quotation offer moved lower (from 10.07 to 10.05) before the one second time period expired. Order 1 did not slide when the Protected Quotation offer moved higher (from 10.05 to 10.07). If, alternatively, the User had elected to have its order cancelled rather than electing price slide, Order 1 would have been cancelled immediately following the Protected Quotation offer's movement from 10.07 to 10.05.

Example 4

A Non-Displayed ISO will remain posted and ranked at the crossing price for the entirety of the one second time period if the Protected Quotation bid moves lower (for sell orders) or offer moves higher (for buy orders) before the one second time period expires.

NBBO: 10.00 x 10.05.

Order 1: Buy 100 at 10.06—Non-Displayed, ISO, price slide, time-in-force Day. Timestamp 12:00:00:000. Order 1 is posted to the BZX at a ranked price of 10.06.

NBBO: 10.01 x 10.06. Timestamp 12:00:00:500.

RESULT: Under proposed Rule 11.9(d)(2)(iii), Order 1 will remain posted and ranked at the crossing price (10.06) because the Protected Quotation offer moved higher (from 10.05 to 10.06) before the expiration of the one second time period.

The Exchange notes that at least one other exchange¹⁵ offers the ability to submit ISOs containing a Non-Displayed instruction with a time-in-force other than IOC and does not believe that its proposal introduces a novel order type. Additionally, the Exchange's proposal to permit a Non-Displayed ISO entered with a time-in-force other than IOC to cross a Protected Quotation for up to one second following receipt by the Exchange is intended to provide clarity into the Exchange's treatment of a Non-Displayed ISO entered with a time-in-force other than IOC that crosses a Protected Quotation after the User's simultaneously routed IOC orders to away market centers did not clear the Protected Quotation. While the

¹⁵ See, e.g., Nasdaq Equity 4, Rule 4702(b)(3)(C) and Nasdaq Equity 4, Rule 4703(j).

Exchange's proposal to permit a Non-Displayed ISO to execute at a price that trades through a Protected Quotation for up to one second following receipt of the order by the Exchange may be a novel concept, the Exchange believes that it is reasonable to permit a Non-Displayed ISO with a time-in-force other than IOC to exist at a crossing price for a short period of time following receipt of the order by the Exchange due to the non-displayed nature of the order, which allows the order to lock or cross a Protected Quotation under Regulation NMS. By limiting the permissible time frame of execution at a price that would trade through a Protected Quotation, the Exchange is attempting to balance the intent of the Order Protection Rule with the characteristics of the Non-Displayed ISO that make this order type attractive to Members.

Non-Displayed Order Behavior

The Exchange currently permits orders to be entered as Non-Displayed Orders pursuant to Rule 11.9(c)(11). The Exchange now proposes to amend Rule 11.9(c)(11) and Rule 11.13(a)(4)(C)–(D) in order to more accurately describe the price at which a Non-Displayed Order posts to the BZX Book and at what price a Non-Displayed Order may execute in certain situations. The Exchange believes the below changes to Rule 11.9(c)(11) and Rule 11.13(a)(4)(C)–(D) are necessary in order to provide market participants with greater certainty and clarity regarding the entry and execution of orders with Non-Displayed instructions on the Exchange.¹⁶

The Exchange proposes to introduce Rule 11.9(c)(11)(A), which provides that when a Non-Displayed Order is entered, the Non-Displayed Order will be executed against previously posted orders on the BZX Book that are priced equal to or better than the price of the Non-Displayed Order, up to the full amount of such previously posted orders, unless such executions would trade through a Protected Quotation. Any portion of a Non-Displayed Order that cannot be executed in this manner will be posted to the BZX Book (unless the Non-Displayed Order has a time-in-force of IOC) and/or routed if it has been designated as a routable order.

The Exchange next proposes to introduce Rule 11.9(c)(11)(B), which describes the price at which a Non-Displayed Order is posted and ranked

on the BZX Book in the event that it is not executed pursuant to proposed Rule 11.9(c)(11)(A). Proposed Rule 11.9(c)(11)(B)(i) provides if the limit price of a Non-Displayed Order would lock either a Protected Quotation or the BZX Book, the Non-Displayed Order will be posted on the BZX Book at the locking price and will be executed as set forth in Rule 11.13(a)(4)(C). If, however, an inbound Non-Displayed Order cannot execute due to User instruction and does not contain a price slide instruction, the Non-Displayed Order will be cancelled. An inbound Non-Displayed Order that cannot execute upon entry and contains a price slide instruction will be ranked at the locking price upon entry. Proposed Rule 11.9(c)(11)(B)(ii) provides if the limit price of the Non-Displayed Order would cross a Protected Quotation and the Non-Displayed Order contains a price slide instruction, the Non-Displayed Order will be executed as set forth in Rule 11.9(g)(4) or cancel, based on User instruction. If the entered limit price of the Non-Displayed Order would cross a Protected Quotation and the Non-Displayed Order does not contain a price slide instruction, the Non-Displayed Order will cancel or route, based on User instruction. Proposed Rule 11.9(c)(11)(B)(iii) provides in situations where there is a resting Non-Displayed Order on the buy (sell) side of the market and an incoming Non-Displayed Order on the sell (buy) side of the market is unable to execute due to User instruction and posts to the BZX Book at a price that locks the resting Non-Displayed Order, an incoming Non-Displayed Order on the buy (sell) side of the market may execute with the resting Non-Displayed Order on the sell (buy) side of the market at the locking price ahead of the Non-Displayed Order on the buy (sell) side of the market.

In conjunction with the proposed changes to Rule 11.9(c)(11), the Exchange also proposes to amend Rule 11.13(a)(4)(C)–(D) to better describe the execution of Non-Displayed Orders in situations where a locked market exists on the BZX Book. Rule 11.13(a)(4)(C) currently states that certain orders are permitted to post and rest on the BZX Book at prices that lock contra-side liquidity, provided, however, that the System will never display a locked market. The Exchange proposes to add language to Rule 11.13(a)(4)(C) to provide that consistent with Rule 11.12, which sets forth the Exchange's rule regarding priority of orders, Non-Displayed Orders and orders subject to display-price sliding as set forth in Rule 11.9(g)(1) (defined as the "Resting

Orders") cannot be executed pursuant to Rule 11.13 when such Resting Orders would be executed at prices equal to displayed orders on the opposite side of the market (the "Locking Price").¹⁷ The Exchange also proposes to amend Rule 11.13(a)(4)(D) to conform with the proposed changes in Rule 11.13(a)(4)(C) with regard to the use of the terms Resting Order and Locking Price. Proposed Rule 11.13(a)(4)(D) will be revised from its current text to provide that in the event that an incoming order described in sub-paragraphs (A) and (B) is a Market Order or is a Limit Order priced more aggressively than the Locking Price of a Resting Order as described in sub-paragraph (C), the Exchange will execute the Resting Order at, in the case of a Resting Order bid, one-half minimum price variation less than the Locking Price, and, in the case of a Resting Order offer, one-half minimum price variation more than the Locking Price.

Implementation

The Exchange proposes to implement the proposed functionality during the first half of 2026 and will announce the date via Trade Desk Notice.

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.¹⁸ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁹ requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with

¹⁷ Any incoming order that would execute against the Resting Order at the Locking Price would receive a priority advantage over the displayed order at the Locking Price. As such, the Exchange does not execute a Resting Order against an incoming order at the Locking Price if there is also a displayed order resting on the EDGX Book at the Locking Price.

¹⁸ 15 U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(5).

¹⁶ The Exchange notes that it has introduced identical language regarding Non-Displayed Order behavior in a proposal on its affiliate exchange, Cboe EDGX Exchange, Inc. See Securities Exchange Act Release No. 104153 (September 30, 2025), 90 FR 48098 (October 3, 2025), SR-CboeEDGX-2025-072 ("EDGX RPI Proposal").

the Section 6(b)(5)²⁰ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that its proposal to amend Rule 11.9(d) to permit Non-Displayed ISOs and proposed amendments to Rule 11.9(c)(11) and Rule 11.13(a)(4)(C)–(D) in order to more accurately describe Non-Displayed Order behavior in certain situations is designed to promote just and equitable principles of trade, help to facilitate transactions in securities and remove impediments to and perfect the mechanism of a free and open market and national market system by providing Users with additional transparency into behavior of Non-Displayed Orders, including Non-Displayed ISOs entered with a time-in-force other than IOC, during locked and crossed markets.

The Exchange's proposal to permit the entry of Non-Displayed ISOs promotes just and equitable principles of trade, helps to facilitate transactions in securities, and removes impediments to and perfects the mechanism of a free and open market and national market system by providing Users with an additional manner in which to enter an ISO with a time-in-force other than IOC. While the Exchange currently supports the usage of displayed ISOs with a time-in-force other than IOC, Users have a wide variety of trading strategies that they may seek to implement across various market centers and the Exchange is seeking to add the ability for Users to enter orders in a non-displayed capacity in order to enhance the usefulness of the order type and to allow the exchange to better compete with at least one other national securities exchange that currently offers the ability to enter an ISO with a non-displayed instruction.²¹ The Exchange notes that entering an ISO as a Non-Displayed Order is completely optional, and Users are in the best position to determine whether the proposed functionality is appropriate and consistent with a User's given trading strategy. By providing Users with this additional order type and allowing the User to decide whether the Non-Displayed ISO is an appropriate order type for the User's trading strategies, the Exchange is removing impediments to and perfecting the mechanism of a free and open marketplace.

Further, the Exchange's proposal to permit a Non-Displayed ISO entered with a time-in-force other than IOC to post to the BZX Book at a price that

crosses a Protected Quotation promotes just and equitable principles of trade by allowing the System to briefly allow a crossed market in limited situations. As described in Regulation NMS, a User that enters an ISO is representing that it has also simultaneously routed one or more additional limit orders to execute against the full displayed size of any protected bid (in the case of a limit order to sell), or the full displayed size of any protected offer (in the case of a limit order to buy) for the security, which indicates that at the time that the Exchange receives the ISO, the Exchange may rely on the User's representation and execute the order at the limit price of the ISO. If an ISO contains a time-in-force other than IOC and is not filled in its entirety, the balance of the order will post to the BZX Book.

In the event that the User's simultaneously routed orders also marked ISO did not execute against the full displayed size of the protected bid (offer) due to executing against hidden liquidity, it is possible to end up in a scenario with a displayed ISO crossing a Protected Quotation. While a displayed ISO may lock or cross a Protected Quotation today, the locked or crossed market is generally resolved quickly once the NBBO updates to reflect the locked or crossed market. However, with a Non-Displayed ISO, the NBBO will not update and market participants would be unaware of a crossed market that needs to be resolved. Thus, the Exchange has proposed to allow the non-displayed crossed market to exist for up to one second before sliding a Non-Displayed ISO to the locking price pursuant to Rule 11.9(g)(4). By allowing the crossed market to exist for up to one second, the Exchange is promoting just and equitable principles of trade by honoring the User's representation that it simultaneously routed orders to clear the full, displayed size of any Protected Quotation in the security with a price that is superior to the limit price of the Non-Displayed ISO, while also giving the market ample time to potentially resolve the crossed market. The Exchange is proposing to amend the ranked price of a Non-Displayed ISO only when the Protected Quotation moves against the price of the Non-Displayed ISO (e.g., if the Protected Quotation bid becomes higher for sell orders or the Protected Quotation offer becomes lower for buy orders). The Exchange believes that amending the ranked price of a Non-Displayed ISO if the Protected Quotation moves against the price of the Non-Displayed ISO

before the expiration of the one-second period is appropriate because it shows that the crossed market is moving in a direction where the cross is unlikely to be resolved. By immediately amending the ranked price of the Non-Displayed ISO to the locking price of the crossed market if the Protected Quotation moves against the price of the Non-Displayed ISO before the one-second period expires, the Exchange believes it is promoting just and equitable principles of trade by taking immediate action to resolve the crossed market that is unlikely to resolve on its own. The Exchange's proposal to slide the Non-Displayed ISO to the locking price if the crossed market is unchanged after one second is not novel, as this price sliding behavior is already contemplated pursuant to Rule 11.9(g)(4) and simply seeks to apply an existing price sliding principle to a Non-Displayed ISO with a time-in-force other than IOC at the conclusion of the one second period.

The Exchange believes its proposal to introduce additional rule text describing the entry and execution of Non-Displayed Orders on the Exchange promotes just and equitable principles of trade by providing additional clarity and transparency to market participants on how the System processes Non-Displayed Orders. Specifically, the Exchange is providing additional information regarding the price at which a Non-Displayed Order is posted and ranked on the BZX Book when a Non-Displayed Order either locks or crosses a Protected Quotation or when a Non-Displayed Order locks the BZX Book. By introducing the proposed rule text, Users will have a better understanding of how a Non-Displayed Order is posted and ranked during certain scenarios involving locked and crossed markets, which benefits all Users and the marketplace as a whole. In addition, the Exchange believes its proposal to introduce additional rule text describing the entry and execution of Non-Displayed Orders on the Exchange is not unfairly discriminatory as all Users and market participants will be subject to the same application of the Exchange's rules and will have equal access to the Exchange rulebook.

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. To the contrary, the Exchange's proposal to introduce a Non-Displayed ISO is a competitive response to a similar order type offered on at least one other

²⁰ *Id.*

²¹ *Supra* note 15.

exchange. As with other national securities exchanges, the Exchange must continually assess and improve its offerings to compete with other exchanges and market centers. The proposed rule change is indicative of this competition. Further, the Exchange does not believe that the proposed rule change would implicate any intramarket competitive concerns with respect to its Users. The proposed ability to enter an ISO with a non-displayed instruction is completely voluntary and available to all Users on an equal and non-discriminatory basis. Rather than impede competition, the proposed rule change would provide an additional order type for Users to facilitate their trading goals.

Additionally, the proposed change regarding Non-Displayed Order entry and execution is not being made for competitive reasons, but rather to provide Users with additional clarity and transparency about what price a Non-Displayed Order is posted and ranked during certain scenarios involving locked and crossed markets.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or

- Send an email to rule-comments@sec.gov. Please include file number SR-CboeBZX-2025-142 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-CboeBZX-2025-142. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-CboeBZX-2025-142 and should be submitted on or before December 19, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Stephanie J. Fouse,

Assistant Secretary.

[FR Doc. 2025-21396 Filed 11-26-25; 8:45 am]

BILLING CODE 8011-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36856]

Providence and Worcester Railroad Company—Operation Exemption—State of Connecticut

Providence and Worcester Railroad Company (P&W), a Class III railroad, has filed a verified notice of exemption pursuant to 49 CFR 1150.41 to enter into an operating agreement with the State of Connecticut (the State) to operate approximately 16.84 miles of railroad known as the Middletown Cluster, consisting of the following lines (collectively, the Line): (1) the Cromwell Industrial Track from its connection to the Laurel Industrial Track in Middletown (approximately milepost 22.34) north along the west side of the Connecticut River to the end of the line in Cromwell, Conn. (approximately

milepost 24.35);¹ (2) the East Berlin Industrial Track in Middletown, Conn., from its point of connection to the Cromwell Industrial Track (approximately milepost 0.0) to the end of the line (approximately milepost 1.0); (3) the Laurel Industrial Track from its connection to the Middletown Secondary on the west side of the Connecticut River Swing Bridge (approximately milepost 0.0) south along the west side of the Connecticut River to the end of the line in Laurel, Middletown Township, Conn. (approximately milepost 5.47); (4) the Middletown Secondary from a point approximately 4,330 feet south of the centerline of Route 157—Overhead Bridge No. 17.71 in Reed's Gap, Durham Township, Conn. (approximately milepost 14.99) to the west side of the Connecticut River Swing Bridge (approximately milepost 22.34); and (5) the Portland Industrial Track from the west side of the Connecticut River Swing Bridge, its connection to the Middletown Secondary in Middletown (approximately milepost 0.0) to the easterly side of Marlboro Street in Portland, Conn. (approximately milepost 1.01).

According to the verified notice, the State owns the Line, and P&W currently operates the Line as a successor in interest to Connecticut Central Railroad Company, Inc. (CCR).² P&W states that CCR began operating the Line in 1987.³ The verified notice states that P&W and the State have entered into a new operating agreement that will replace the prior operating agreement. P&W explains that it will continue to operate the Line under the new operating agreement, which is for a twenty-year term with up to two ten-year extensions. The verified notice notes that as the successor to CCR, P&W also currently

¹ The verified notice states that the mileposts have been revised in order to reflect the current designation.

² See *Providence & Worcester R.R.—Acquis. & Operation Exemption—Conn. Cent. R.R.*, FD 33527, slip op. at 1, 3 (STB served Mar. 3, 1998) (exempting from prior approval requirements P&W's acquisition and operation of CCR); *Providence & Worcester R.R.—Corp. Fam. Transaction Exemption—Conn. Cent. R.R.*, FD 33592, slip op. at 1 (STB served May 15, 1998) (giving notice that CCR will merge into P&W in exempt intra-corporate family transaction).

³ See *Conn. Cent. R.R.—Operation Exemption—Certain Lines of the State of Conn.*, FD 31045, slip op. at 1–2 (ICC served June 3, 1987). P&W represents that “P&W and the State extended the original operating agreement, but it does not appear that Board authorization was sought, and P&W is not now seeking retroactive authority.” The class exemption invoked by P&W does not provide for retroactive effectiveness. See *Cent. N.Y. R.R.—Lease & Operation Exemption Including Interchange Commitment—Norfolk S. Ry.*, FD 36825, slip op. at 2 n.3 (STB served Mar. 28, 2025).

²² 17 CFR 200.30–3(a)(12).

operates the State's approximately 11.49-mile Wethersfield Secondary rail line pursuant to a modified certificate,⁴ and further states that this arrangement will continue under the new operating agreement.⁵ According to the verified notice, the new operating agreement will be effective on the effective date of the exemption.

The verified notice states that the new operating agreement does not include an interchange commitment. P&W further certifies that its projected annual revenues due to this transaction will not result in the creation of a Class II or Class I rail carrier.

P&W certifies that its revenues currently exceed \$5 million. Pursuant to 49 CFR 1150.42(e), if a carrier's projected annual revenues will exceed \$5 million, it must, at least 60 days before this exemption is to become effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. However, P&W's verified notice of exemption includes a request for waiver of the 60-day advance labor notice requirement so that the exemption can become effective 30 days after the verified notice was filed. P&W's waiver request will be addressed in a separate decision. The Board will establish the effective date of the exemption in its separate decision on the waiver request.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 5, 2025.

All pleadings, referring to Docket No. FD 36856, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on P&W's representative, Justin J. Marks, Clark Hill PLC, 1001 Pennsylvania Ave. NW, Suite 1300 South, Washington, DC 20004.

⁴ See *Conn. Cent. R.R.—Modified Rail Certificate*, FD 33125, slip op. at 1–2 (STB served Oct. 17, 1996); *Conn. Cent. R.R.—Modified Rail Certificate*, FD 33515, slip op. at 1 (STB served Dec. 22, 1997).

⁵ Board approval is not required for lease amendments or extensions where the subject line is operated under a modified certificate of public convenience and necessity. *Vt. Ry.—Modified Rail Certificate*, FD 34455, slip op. at 2 (STB served Jan. 27, 2004).

According to P&W, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: November 24, 2025.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Kenyatta Clay,
Clearance Clerk.

[FR Doc. 2025–21376 Filed 11–26–25; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36885]

Arkansas Midland Railroad Company, Inc.—Lease and Operation Exemption Including Interchange Commitment—Union Pacific Railroad Company

Arkansas Midland Railroad Company, Inc. (AKMD), a Class III railroad, has filed a verified notice of exemption under 49 CFR 1150.41 to extend the term of, and to make other changes to, its lease agreement with Union Pacific Railroad Company (UP). Pursuant to that agreement, AKMD leases and operates the following rail lines totaling approximately 57.6 miles (the Leased Lines): (1) a portion of the Carlisle Industrial Lead from UP's milepost 130.33 to the end of the line at UP's milepost 131.38, including side tracks appurtenant thereto; (2) rail line extending between UP's milepost 292.00 and UP's milepost 297.93, including side tracks appurtenant thereto, connecting with UP's mainline in North Little Rock Yard near milepost 343.40; (3) the Warren Line extending between a connection with UP at milepost 422.32 in Dermott, Ark., and milepost 461.74 at Warren, Ark.; (4) the Cypress Bend Industrial Lead, between milepost 407.5 at McGehee, Ark., and milepost 399.7 at Cypress Bend, Ark.; and (5) the Potlatch Spur, between milepost 0.0 (milepost 399.7 on the Cypress Bend Industrial Lead), and approximately milepost 3.4.¹

According to the verified notice, in 2000, AKMD entered into an agreement with UP to lease and operate certain segments of the Leased Lines. See *Ark. Midland R.R.—Lease & Operation Exemption—Union Pac. R.R.*, FD 33908

¹ The verified notice states that the lease also includes the yard at the east end of the Potlatch Spur and portions of the McGehee Yard (except yard tracks 001 and 002) as well as incidental bridge trackage rights over UP's rail line between milepost 406.5 at McGehee and milepost 415.26 at Dermott.

(STB served Aug. 23, 2000). The parties subsequently supplemented that lease to allow AKMD to lease and operate the other portions of the Leased Lines. See *Ark. Midland R.R.—Change in Operators Exemption—Line of Union Pac. R.R.*, FD 34567 (STB served Nov. 17, 2004); *Ark. Midland R.R.—Lease & Operation Exemption—Union Pac. R.R.*, FD 34714 (STB served Aug. 30, 2005). According to the verified notice, the parties also subsequently supplemented the lease to extend the term of the lease to allow the parties to negotiate the supplement that is the subject of the verified notice. The verified notice indicates that AKMD and UP have now agreed to amend the lease to further extend its term and make other commercial changes. AKMD states that it will continue to operate the Leased Lines.

AKMD certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier and that its annual revenues currently exceed \$5 million. Pursuant to 49 CFR 1150.42(e), if a carrier's projected annual revenues will exceed \$5 million, it must, at least 60 days before the exemption becomes effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. However, AKMD has filed a request for waiver of the 60-day advance labor notice requirements to allow the exemption to take effect 30 days after the filing of AKMD's verified notice of exemption. AKMD's waiver request will be addressed in a separate decision. The Board will establish the effective date of the exemption in its separate decision on the waiver request.

AKMD certifies that the lease contains an existing interchange commitment. AKMD has provided additional information regarding the interchange commitment, as required by 49 CFR 1150.43(h).²

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 5, 2025.

² AKMD filed a copy of the agreement, including all supplements, under seal with the verified notice. See 49 CFR 1150.43(h)(1).

All pleadings, referring to Docket No. FD 36885, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on AKMD's representative, Justin J. Marks, Clark Hill PLC, 1001 Pennsylvania Ave. NW, Suite 1300 South, Washington, DC 20004.

According to AKMD, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: November 21, 2025.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Kenyatta Clay,
Clearance Clerk.

[FR Doc. 2025-21386 Filed 11-26-25; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA-2025-1174; Summary Notice No.—2025-63]

Petition for Exemption; Summary of Petition Received; Rotor Technologies, Inc.

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 29, 2025.

ADDRESSES: Send comments identified by docket number [FAA-2025-1174] using any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://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 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- **Fax:** Fax comments to Docket Operations at (202) 493-2251.

Privacy: 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 <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

Docket: Background documents or comments received may be read at <http://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 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 267-2928, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Dan A. Ngo,

Manager, Part 11 Petitions Branch, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2025-1174.

Petitioner: Rotor Technologies, Inc.

Section(s) of 14 CFR Affected:

§§ 61.3(c)(1), 61.23(a)(2), 91.7(a), 91.9(b)(1), 91.121, 91.225(h)(2), 91.403(a), 91.403(b), 91.405(a), 91.407(a)(1), 91.409(a)(1), 91.409(a)(2), 91.417(a), 91.417(b), 137.19(c), 137.19(d), 137.31(b), 137.33(a), 137.33(b), 137.41(c), and 137.42.

Description of Relief Sought: Rotor Technologies, Inc. seeks relief to operate the Rotor R220 and Rotor R550, rotor-wing unmanned aircraft systems (UAS) with maximum takeoff weights (MTOW) of 1,360 pounds (lbs.) and 2,500 lbs. respectively, for agricultural spraying operations in remote rural operating environments in the United States. All

operations will occur during daylight hours and within visual line-of-sight (VLOS) of a trained pilot-in-command (PIC) or visual observer (VO).

[FR Doc. 2025-21459 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA-2025-0780]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Service Availability Prediction Tool (SAPT)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves planned routes of flight and aircraft avionics equipment. The information to be collected will be used to predict whether an aircraft flying the proposed route of flight will have sufficient position accuracy and integrity for the following: Navigation, via the Receiver Autonomous Integrity Monitoring (RAIM) SAPT; Surveillance, via the Automatic Dependent Surveillance—Broadcast (ADS-B) SAPT. In addition, the website will allow operators to request authorization to operate in ADS-B-Out rule airspace with aircraft that do not fully meet the ADS-B Out requirements via: ADS-B Deviation Authorization Pre-flight Tool (ADAPT).

DATES: Written comments should be submitted by January 27, 2026.

ADDRESSES: Please send written comments:

By Electronic Docket:
www.reginfo.gov/public/do/PRAMain
(Enter docket number into search field).

By email: Mr. Jamal A. Wilson by email at jamal.wilson@faa.gov; phone: (202) 267-4301.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Mr. James Kenney by email at james.kenny@faa.gov; phone: (703) 624-3695.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of

information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120-0780.

Title: Service Availability Prediction Tool (SAPT).

Form Numbers: eXtensible markup language (XML) format, ADS-B SAPT flight information entry form, and ADS-B authorization request at <https://sapt.faa.gov>.

Type of Review: Renewal of an information collection.

Background:

Under 14 CFR 91.103, pilots must use all available information in planning their flight. SAPT is a web-based tool to assist aircraft operators in achieving compliance with the requirements of 14 CFR 91.103, 91.225, and 91.227, and/or AC 90-100A Change 2, Paragraph 10a. (5). To ensure that they will meet the performance requirements for the duration of the flight, pilots may use the FAA-provided pre-flight Service Availability Prediction Tool (SAPT) to determine predicted navigation or surveillance availability before a flight. The SAPT has three main components: the Receiver Autonomous Integrity Monitoring (RAIM) SAPT, the ADS-B SAPT, and the ADS-B Deviation Authorization Pre-Flight Tool (ADAPT). The SAPT models the GPS constellation in order to assess the predicted accuracy and integrity of GPS position information used in navigation and surveillance for a few GPS receiver Technical Standard Orders (TSOs).

The RAIM SAPT is intended mainly for pilots, dispatchers, and commercial operators using TSO-C129 equipment to check their predicted navigation horizontal protection level (HPL). It incorporates TSO-C129 GPS RAIM predictions to check the availability of GPS RAIM satisfying the RNAV requirements of AC 90-100A Change 2, Paragraph 10(5)).

The ADS-B SAPT is provided to help operators comply with 14 CFR 91.225 and 91.227 by predicting whether operators will meet regulatory requirements.

Information collected via ADS-B SAPT is comparable to that provided by pilots when they file flight plans, with some additional information about aircraft position source TSO and related

capabilities. The ADS-B SAPT prediction is based on the ability of the aircraft's position source (*i.e.*, GPS receiver) to meet performance requirements specified in FAA TSOs C129, C129a, C145c/C146c, and C196, as well as the predicted status of the GPS constellation.

The ADS-B SAPT predicts whether GPS position information will be sufficient throughout the flight to meet the performance requirements of 14 CFR 91.227(c)(1)(i) and (iii). If a waypoint is in rule airspace and the aircraft's position source is not predicted to meet the performance requirements of 14 CFR 91.227, the ADS-B SAPT checks for the availability of back-up surveillance at that waypoint.

Operators of aircraft equipped with TSO-C129 (SA-On) GPS receivers must run a pre-flight prediction. The operator may use their own prediction tool.

ADAPT is mandatory for operators desiring to apply for an ATC authorization, per 14 CFR 91.225(g), to fly in ADS-B Out rule airspace using aircraft with avionics that do not meet the ADS-B equipage requirements. ADAPT allows operators to create an air traffic authorization request to operate in ADS-B Out rule airspace when (1) the aircraft is without ADS-B equipment; (2) that equipment is inoperative; or (3) their avionics are not expected to meet the ADS-B performance requirements as identified in 14 CFR 91.227(c)(1)(i) and (iii). Operators who wish to submit an ADAPT request must complete the ADS-B SAPT analysis using information entered into the flight information entry form before filing the ADAPT request.

Information Collected

Information collected by SAPT is comparable to that provided in FAA flight plans, with some additional information about the position source. The ADS-B SAPT flight information entry form requires the aircraft call sign but does not collect other personal identification information about the operator. ADAPT does collect personal information to include name, telephone number, email address. The information is necessary to enable the FAA ATC Authorization Authority (AAA) to reply with either an approval, rejection, or pending decision. It also collects additional information about the flight, including US Civil Aircraft Registry Number or ICAO Address.

Respondents

These prediction tools are primarily intended for pilots and dispatchers; and

for anyone who is planning a flight which passes through U.S. sovereign airspace, using an aircraft whose GPS receiver(s) is/are not guaranteed to meet certain performance requirements or whose aircraft is not equipped to meet the requirements of 14 CFR 91.225. Since SAPT does not collect personal information from either ADS-B SAPT or RAIM users, we do not have transactions assigned to individual respondents.

Frequency

As part of the flight planning process, as required by FAA policy. Predictions are made in evaluating a route of flight, which may be more than one route per flight. We estimate that the total 2026 levels will be:

Automated transactions, requiring insignificant effort per transaction:

- RAIM SAPT—3,792,901
- ADS-B SAPT—9,667,021

Manual web transactions:

- ADS-B SAPT Web Form—18,102 transactions, approximately 885 hours.
- ADAPT—4,823 transactions, including DoD/military, which takes approximately 344 hours.

Estimated Average Burden per Response

RAIM SAPT and ADS-B SAPT can be automated as part of the dispatch process by operators or flight service providers, thus eliminating manual data-entry.

RAIM SAPT—Insignificant, as all transactions are automated in flight planning systems.

ADS-B SAPT—5 minutes or less for transactions entered in the flight plan form.

ADAPT—7 minutes or less (includes up to 2 minutes to check FAA email response).

Estimated Total Annual Burden

Cumulative total burden for 2026:

RAIM SAPT—Insignificant additional burden.

ADS-B SAPT—Approximately 1,207 hours (for reporting) and 302 hours (for record-keeping).

ADAPT—Approximately 402 hours (for reporting) and 80 hours (for record-keeping).

Issued in Washington, DC.

Jamal Abdul Wilson,

Project Manager, AJM-42, ADS-B Program Office, PMO Surveillance Services, Air Traffic Organization, FAA.

[FR Doc. 2025-21349 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration**

[Docket No. FMCSA–2014–0385; FMCSA–2014–0386; FMCSA–2021–0014; FMCSA–2023–0020; FMCSA–2023–0021]

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 six 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: The exemptions were applicable on September 12, 2025. The exemptions expire on September 12, 2027. Comments must be received on or before December 29, 2025.

ADDRESSES: You may submit comments identified by Docket No. FMCSA–2014–0385, FMCSA–2014–0386, FMCSA–2021–0014, FMCSA–2023–0020, or FMCSA–2023–0021, as appropriate, using any of the following methods:

- **Federal eRulemaking Portal:** Go to www.regulations.gov, insert the docket number (FMCSA–2014–0385, FMCSA–2014–0386, FMCSA–2021–0014, FMCSA–2023–0020, or FMCSA–2023–0021) 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. Evangela Hollowell, Acting Chief,

Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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–2014–0385, FMCSA–2014–0386, FMCSA–2021–0014, FMCSA–2023–0020, or FMCSA–2023–0021), 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–2014–0385, FMCSA–2014–0386, FMCSA–2021–0014, FMCSA–2023–0020, or FMCSA–2023–0021) 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. Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the

notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as “PROPIN” to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at brian.g.dahlin@dot.gov. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

C. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA–2014–0385, FMCSA–2014–0386, FMCSA–2021–0014, FMCSA–2023–0020, or FMCSA–2023–0021) 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.

D. 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, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System), which can be reviewed under the “Department Wide System of Records Notices” link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor

Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

III. Background

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)).

The six 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.

IV. 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.

V. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the six applicants have satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The six drivers in this notice remain in good standing with the Agency. In addition, the Agency has reviewed each applicant's certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Accordingly, 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 equivalent to that existing without the exemption.

As of September 12, 2025, 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:

Daniel Alcozer (IL)
Loir Greenidge (IA)
Kenneth Lloyd (PA)
Tia Matthews (TX)
Eduwin Pineiro (NJ)
Jason Swearington (TX)

The drivers were included in docket number FMCSA–2014–0385, FMCSA–

2014–0386, FMCSA–2021–0014, FMCSA–2023–0020, or FMCSA–2023–0021. Their exemptions were applicable as of September 12, 2025, and will expire on September 12, 2027.

VI. Terms and Conditions

The exemptions are extended subject to the following conditions: each driver (1) must report to FMCSA any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391, within 7 days of the citation and conviction; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all the applicable commercial driver's license 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).

VII. 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.

VIII. Conclusion

Based upon its evaluation of the six exemption renewal applications, FMCSA renews the exemptions of the above-named drivers from the hearing requirement in § 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21420 Filed 11–26–25; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration**

[Docket No. FMCSA–2013–0124; FMCSA–2014–0103; FMCSA–2014–0106; FMCSA–2014–0385; FMCSA–2015–0329; FMCSA–2016–0002; FMCSA–2017–0058; FMCSA–2018–0135; FMCSA–2018–0136; FMCSA–2018–0137; FMCSA–2020–0027; FMCSA–2022–0036; FMCSA–2022–0037; FMCSA–2023–0018]

Qualification of Drivers; Exemption Applications; Hearing

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 17 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.

FOR FURTHER INFORMATION CONTACT: Ms. Evangelina Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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. Viewing Comments**

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA–2013–0124, FMCSA–2014–0103, FMCSA–2014–0106, FMCSA–2014–0385, FMCSA–2015–0329, FMCSA–2016–0002, FMCSA–2017–0058, FMCSA–2018–0135, FMCSA–2018–0136, FMCSA–2018–0137, FMCSA–2020–0027, FMCSA–2022–0036, FMCSA–2022–0037, or FMCSA–2023–0018) 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.

B. 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, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System), which can be reviewed under the “Department Wide System of Records Notices” link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant’s safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver’s medical certification.

III. Background

On May 5, 2025, FMCSA published a notice announcing its decision to renew exemptions for 17 individuals from the hearing standard in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (90 FR 19069). The public comment period ended on June 4, 2025, and no comments were received.

The Agency evaluated the eligibility and determined that renewing these exemptions would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing, found in § 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)).

IV. Discussion of Comments

FMCSA received no comments in this proceeding.

V. Basis for Exemption Determination

The Agency’s decision regarding these exemption applications is based on relevant scientific information and literature, and the 2008 Evidence Report, “Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety.”¹ The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) no studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver’s license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant’s

¹ <https://www.fmcsa.dot.gov/regulations/medical/hearing-vestibular-function-and-commercial-motor-vehicle-driver-safety-executive>.

certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is used as an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. Each applicant's record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equivalent or greater level of safety would likely be achieved by permitting each of these drivers to drive in interstate commerce, the Agency did not find any evidence that the drivers granted this exemption pose a risk to public safety.

Consequently, FMCSA further finds that in each case exempting these applicants from the hearing standard in § 391.41(b)(11) would likely achieve a level of safety equivalent to the level of safety that would be achieved without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

VI. Terms and Conditions

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: each driver (1) must report to FMCSA the date, location, and time of any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 within 7 days of the citations and convictions; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all applicable commercial driver's license testing requirements.

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 17 renewal exemption applications, FMCSA announces its decision to grant a 2-year exemption to each of the following drivers from the hearing requirement in § 391.41(b)(11).

As of April 21, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, the following 15 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Ivan Batista (NJ)
Prince K. Bemping (MA)
Richard Boggs (OH)
Keith Byrd (TN)
Joshua Cogan (MD)
Joseph Conversa (IL)
Brandon Hester (TX)
Paradise Larizza (CA)
Reynaldo Martinez (TX)
Floyd McClain (OH)
Dustin R. Miller (MI)
David Sanders (IL)
Jesse Shelander (TX)
John Turner, III (CO)
Brandon Veronie (LA)

The drivers were included in docket number FMCSA–2013–0124, FMCSA–2014–0103, FMCSA–2014–0106, FMCSA–2014–0385, FMCSA–2015–0329, FMCSA–2016–0002, FMCSA–2017–0058, FMCSA–2018–0135, FMCSA–2018–0136, FMCSA–2018–0137, FMCSA–2020–0027, FMCSA–2022–0036, or FMCSA–2022–0037. Their exemptions were applicable as of April 21, 2025, and will expire on April 21, 2027.

As of April 26, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers: Freddy Lopez Hernandez (TX); and Martin Vorpahl (WI).

The drivers were included in docket number FMCSA–2023–0018. Their exemptions were applicable as of April 26, 2025, and will expire on April 26, 2027.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (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 prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21429 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2025–0023]

Qualification of Drivers; Exemption Applications; Hearing

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 26 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. The exemptions enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on June 9, 2025. The exemptions expire on June 9, 2027.

FOR FURTHER INFORMATION CONTACT: Ms. Evangela Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA–2025–0023) in the keyword box and click “Search.” Next, choose the only 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.

B. 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, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System), which can be reviewed under the “Department Wide System of Records Notices” link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant’s safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver’s medical certification.

III. Background

On May 5, 2025, FMCSA published a notice announcing receipt of applications from 26 individuals requesting an exemption from the

hearing requirement in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (90 FR 19075). The public comment period ended on June 4, 2025, and two comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing, found in § 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)).

IV. Discussion of Comments

FMCSA received two comments in this proceeding. Kelly Moore stated that driver qualification standards should not be determined by jurisdictions, as drivers already undergo medical evaluations as part of the process in receiving a driver’s license. Kelly Moore stated that once a license is obtained, the individual has a legal right to drive without having to justify their ability to other states or counties.

An anonymous commenter stated that hearing-impaired drivers are not suitable candidates for a hazardous materials endorsement because drivers must stop at all railroad crossings to listen for a train in case the signals are inoperative.

In response to Kelly Moore’s comment, FMCSA notes that the FMCSRs establish the physical qualification requirements for drivers who operate CMVs in interstate commerce, including the hearing standard, and that determining whether a driver is physically qualified is not up to each jurisdiction. In response to the anonymous comment, drivers issued a Federal hearing exemption are exempt only from meeting the requirement in 49 CFR 391.41(b)(11). Drivers are not

exempt from meeting requirements to obtain a hazardous materials endorsement on the commercial driver’s license.

V. Basis for Exemption Determination

The Agency’s decision regarding these exemption applications is based on relevant scientific information and literature, and the 2008 Evidence Report, “Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety.”¹ The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) no studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver’s license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant’s certified driving record from their State Driver’s Licensing Agency (SDLA). The information obtained from each applicant’s driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is used as an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. Each applicant’s record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equivalent or greater level of safety would likely be achieved by permitting each of these drivers to drive in interstate commerce, the Agency did not find any evidence that the drivers granted this exemption pose a risk to public safety.

Consequently, FMCSA further finds that in each case exempting these applicants from the hearing standard in § 391.41(b)(11) would likely achieve a level of safety equivalent to the level of safety that would be achieved without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

VI. Terms and Conditions

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: each driver

¹ <https://www.fmcsa.dot.gov/regulations/medical/hearing-vestibular-function-and-commercial-motor-vehicle-driver-safety-executive>.

(1) must report to FMCSA the date, location, and time of any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 within 7 days of the citations and convictions; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all applicable commercial driver's license testing requirements.

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 26 exemption applications, FMCSA exempts the following drivers from the hearing standard; in § 391.41(b)(11), subject to the requirements cited above:

Seydi Annayev (OR)
Robert Ballengee (IA)
Alicia Bartlett (VT)
Charlotte Bolden (IL)
Michael Brissette (TX)
Quavonte Brooks (TX)
Kiara Brown (GA)
Marcus Bryant (CA)
Kimberly Cain (SD)
Zachary Crawford (TX)
Ambrose Dannels (TX)
Robert Erickson (WI)
Israel Gilliam (TX)
Timothy Hogan (TX)
Kirk Johnson (FL)
Randall Johnson (WI)
Dakota Kangas (WI)
Camerson Luttrell (MO)
Shane Martin (AL)
Shellie Overstreet (UT)
Erick Salcido (TX)
Rex Shepard (MD)
Sean Sikes (IN)
Jonna Silvia (RI)
David Warning (RI)
Kerry Werner (FL)

In accordance with 49 U.S.C. 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the

following occurs: (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 prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21424 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2014–0387; FMCSA–2018–0139; FMCSA–2019–0109; FMCSA–2021–0015; FMCA–2023–0022]

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 15 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 December 29, 2025.

ADDRESSES: You may submit comments identified by Docket No. FMCSA–2014–0387, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2021–0015, or FMCSA–2023–0022, as appropriate, using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov, insert the docket number (FMCSA–2014–0387, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2021–0015, or FMCSA–2023–0022) 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. Evangelina Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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–2014–0387, FMCSA–2018–0139, FMCSA–2019–0109,

FMCSA–2021–0015, or FMCSA–2023–0022), 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–2014–0387, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2021–0015, or FMCSA–2023–0022) 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. Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as "PROPIN" to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590-0001 or via email at brian.g.dahlin@dot.gov. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

C. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA-2014-0387, FMCSA-2018-0139, FMCSA-2019-0109, FMCSA-2021-0015, or FMCSA-2023-0022) 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.

D. 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, including any personal information the

commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL-14 FDMS (Federal Docket Management System), which can be reviewed under the "Department Wide System of Records Notices" link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

III. Background

The physical qualification standard for drivers regarding hearing, found in § 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)).

The 15 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.

IV. 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.

V. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 15 applicants have satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 15 drivers in this notice remain in good standing with the Agency. In addition, the Agency has reviewed each applicant's certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. 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 equivalent 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 1, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following five individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Azulita-Jane Camacho (CA)
Robert Culp (FL)
Charles Davis (AL)
Christopher Fisher (WA)
John Price (TX)

The drivers were included in docket number FMCSA–2018–0139. Their exemptions were applicable as of October 1, 2025, and will expire on October 1, 2027.

As of October 2, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following three individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Eric Sheppard (DE); Timothy Szabo (WI); and Perry Wesberry (VA).

The drivers were included in docket number FMCSA–2023–0022. Their exemptions were applicable as of October 2, 2025, and will expire on October 2, 2027.

As of October 8, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following four individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Dareous Glover (IL)
Delroy Hunt (FL)
John Norman (IL)
Kyle Voss (WI)

The drivers were included in docket number FMCSA–2021–0015. Their exemptions were applicable as of October 8, 2025, and will expire on October 8, 2027.

As of October 10, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Kurt Bernabei (IL); and Steven Robelia (TN).

The drivers were included in docket number FMCSA–2019–0109. Their exemptions were applicable as of October 10, 2025, and will expire on October 10, 2027.

As of October 22, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), Clinton Homon (IL) has satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers.

This driver was included in docket number FMCSA–2014–0387. The exemption was applicable as of October 22, 2025, and will expire on October 22, 2027.

VI. Terms and Conditions

The exemptions are extended subject to the following conditions: each driver (1) must report to FMCSA any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391, within 7 days of the citation and conviction; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all the applicable commercial driver's license 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).

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 15 exemption renewal applications, FMCSA renews the exemptions of the above-named drivers from the hearing requirement in § 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21425 Filed 11–26–25; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0154, FMCSA–2014–0383; FMCSA–2014–0384; FMCSA–2017–0058; FMCSA–2018–0136; FMCSA–2018–0138; FMCSA–2020–0027; FMCSA–2021–0014; FMCSA–2022–0032; FMCSA–2022–0035; FMCSA–2023–0018; FMCSA–2023–0020]

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 18 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 December 29, 2025.

ADDRESSES: You may submit comments identified by Docket No. FMCSA–2012–0154, Docket No. FMCSA–2014–0383, Docket No. FMCSA–2014–0384, Docket No. FMCSA–2017–0058, Docket No. FMCSA–2018–0136, Docket No. FMCSA–2018–0138, Docket No. FMCSA–2020–0027, Docket No. FMCSA–2021–0014, Docket No. FMCSA–2022–0032, Docket No. FMCSA–2022–0035, Docket No. FMCSA–2023–0018, or Docket No. FMCSA–2023–0020, as appropriate, using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov, insert the docket number (FMCSA–2012–0154, FMCSA–2014–0383, FMCSA–2014–0384, FMCSA–2017–0058, FMCSA–2018–0136, FMCSA–2018–0138, FMCSA–2020–0027, FMCSA–2021–0014, FMCSA–2022–0032, FMCSA–2022–0035, FMCSA–2023–0018, or FMCSA–2023–0020, as appropriate) 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. Evangela Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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 (FMCSA–2012–0154, FMCSA–2014–0383, FMCSA–2014–0384, FMCSA–2017–0058, FMCSA–2018–0136, FMCSA–2018–0138, FMCSA–2020–0027, FMCSA–2021–0014, FMCSA–2022–0032, FMCSA–2022–0035, FMCSA–2023–0018, or FMCSA–2023–0020), 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–2012–0154, FMCSA–2014–0383, FMCSA–2014–0384, FMCSA–2017–0058, FMCSA–2018–0136, FMCSA–2018–0138, FMCSA–2020–0027, FMCSA–2021–0014, FMCSA–2022–0032, FMCSA–2022–0035, FMCSA–2023–0018, or FMCSA–2023–0020) 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. Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as “PROPIN” to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at brian.g.dahlin@dot.gov. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

C. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA–2012–0154, FMCSA–2014–0383, FMCSA–2014–0384, FMCSA–2017–0058, FMCSA–2018–0136, FMCSA–2018–0138, FMCSA–2020–0027, FMCSA–2021–0014, FMCSA–2022–0032, FMCSA–2022–0035, FMCSA–2023–0018, or FMCSA–2023–0020) 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.

D. 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, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System), which can be reviewed under the “Department Wide System of Records Notices” link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant’s safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver’s medical certification.

III. Background

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)).

The 18 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.

IV. 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.

V. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 18 applicants have satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 18 drivers in this notice remain in good standing with the Agency. In addition, the Agency has reviewed each applicant's certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. These factors provide an adequate basis for predicting each driver's ability to

continue to safely operate a CMV in interstate commerce. Accordingly, 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 equivalent 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 July and are discussed below.

As of July 1, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), Tyjuan Davis (VA) has satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers.

This driver was included in docket number FMCSA–FMCSA–2012–0154. The exemption was applicable as of July 1, 2025, and will expire on July 1, 2027.

As of July 30, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 17 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Selwyn Abrahamson (MN)
Amin Ali (OH)
Vicente Carreon (AZ)
Daniel Cohen (VT)
Eleazar Contreras (IL)
Stephen Goen (GA)
Calvin Gousby (TX)
Michael Hoyt (OR)
Thomas Lipyanic (FL)
Michael Loschen (MI)
Ismail Muse (UT)
Jonas Pittman (NC)
Troy Rolland (TX)
Sandy Sloat (ND)
Jeffrey Webber (OK)
Richard Whittaker (FL)
Rebecca Yeater (FL)

The drivers were included in docket number FMCSA–2014–0383, FMCSA–2014–0384, FMCSA–2017–0058, FMCSA–2018–0136, FMCSA–2018–0138, FMCSA–2020–0027, FMCSA–2021–0014, FMCSA–2022–0032, FMCSA–2022–0035, FMCSA–2023–0018, or FMCSA–2023–0020. Their exemptions were applicable as of July 30, 2025, and will expire on July 30, 2027.

VI. Terms and Conditions

The exemptions are extended subject to the following conditions: each driver (1) must report to FMCSA any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391, within 7 days of the

citation and conviction; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all the applicable commercial driver's license 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).

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 18 exemption renewal applications, FMCSA renews the exemptions of the above-named drivers from the hearing requirement in § 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21428 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2025–0787]

Agency Information Collection Activities; New Information Collection: Quantifying the Benefits of Creating New Truck Parking Spaces

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

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995,

FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval and invites public comment. This notice invites comments on a proposed information collection titled *Quantifying the Benefits of Creating New Truck Parking Spaces*. This research study will collect approximately 1,000 survey responses from truck drivers about their experiences with finding truck parking spaces to estimate the monetary benefits of creating new truck parking spaces.

DATES: Comments on this notice must be received on or before January 27, 2026.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2025–0787 using any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments.

- **Mail:** Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.

- **Hand Delivery or Courier:** Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

- **Fax:** (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Dan Britton, Office of Research and Registration, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–9980; dan.britton@dot.gov.

SUPPLEMENTARY INFORMATION:

Instructions

All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. Note that all comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below.

Public Participation and Request for Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2025–0787), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <https://www.regulations.gov/docket/FMCSA-2025-0787/document>, click on this notice, click “Comment,” and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

FMCSA will consider all comments and material received during the comment period.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, including any personal information the commenter provides, to www.regulations.gov as described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edits and are searchable by the name of the submitter.

Background

The nationwide shortage of truck parking spaces is a significant source of frustration for truck drivers, increasing expenses for the trucking industry and decreasing safety for all road users. The American Transportation Research Institute conducts an annual survey of trucking industry stakeholders (*Critical Issues in the Trucking Industry*), and the 2024 survey found that, for the second year in a row, the lack of available truck parking was the second highest industry concern overall, and the number one concern among truck drivers. The lack of truck parking often forces truck drivers to choose between violating federal hours-of-service laws and using unsafe, illegal parking spaces.

Many government, safety, and industry organizations are working to create more truck parking spaces, but there is a lack of research on the actual precise monetary benefits of new truck parking spaces. These benefits include decreasing carriers’ costs, increasing drivers’ well-being, and reducing the number of crashes. To help State and local policymakers make informed decisions about the construction of truck parking spaces, FMCSA is conducting a research study, titled *Quantifying the Benefits of Creating New Truck Parking Spaces*, which will survey truck drivers about their parking habits and experiences, gaining the exact information needed to quantify the benefits of new truck parking spaces.

Although researchers have conducted many other surveys on truck parking, none have reliably estimated the statistics needed, including how often and how long truck drivers (a) park in unauthorized spaces, (b) stop driving early to obtain a parking space, (c) drive off their routes to find parking, and (d) drive past hours-of-service limits to find parking. The results of this survey will be combined with related research to produce estimates of the benefits of creating new truck parking spaces in different areas, which could be beneficial to the many government and private organizations that decide where to build new truck parking spaces.

The main objective of this project is to estimate the benefits of new truck parking spaces, but the project will also answer four related research questions:

1. How many trucks are parked in authorized and unauthorized areas per day, on average? In other words, how large is the nationwide shortage of truck parking spaces?

2. What are the most cost-effective methods for increasing truck parking capacity?

3. Which truck parking information management systems are used most often and are most effective?

4. What percentage of drivers routinely make reservations, pay for parking, or use various other truck parking services?

Several thousand truck drivers, from a wide range of sectors, will be asked to complete the 25-minute online survey, with a goal of obtaining approximately 1,000 complete responses.

Title 23, United States Code (U.S.C.), Chapter 4, Section 403 authorizes the Secretary to use funds appropriated to carry out this section to conduct research and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and

related information with respect to all aspects of highway and traffic safety systems and conditions relating to vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; and human behavioral factors and their effect on highway and traffic safety, including driver education, impaired driving and distracted driving; and research on, evaluations of, and identification of best practices related to driver education programs (including driver education curricula, instructor training and certification, program administration, and delivery mechanisms) and make recommendations for harmonizing driver education and multistage graduated licensing systems; and the effect of State laws on any aspects, activities, or programs described in subparagraphs (A) through (E) (see 23 U.S.C. 403(b)(1)(A)(i)–(ii), 23 U.S.C. 403(b)(1)(B)(i)–(iii), 23 U.S.C. 403(b)(1)(E), 23 U.S.C. 403(b)(1)(F)).

Title: Quantifying Benefits of Truck Parking.

OMB Control Number: 2126–00XX.

Type of Request: New ICR.

Respondents: Commercial truck drivers.

Estimated Number of Respondents: 1,000.

Estimated Time per Response: 25 minutes.

Expiration Date: N/A. This is a new ICR.

Frequency of Response: Each survey participant will provide only one survey response.

Estimated Total Annual Burden: 416 hours (0.416 hours per response × 1,000 respondents) at an estimated cost of \$15,185.66 (\$15.19 per respondent × 1,000 respondents).

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The Agency will summarize or include your comments in the request for OMB's clearance of this ICR.

Issued under the authority of 49 CFR 1.87.

Jonathan Mueller,

Acting Associate Administrator, Office of Research and Registration.

[FR Doc. 2025–21431 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2014–0102; FMCSA–2014–0107; FMCSA–2014–0385; FMCSA–2021–0015; FMCSA–2022–0034; FMCSA–2022–0035; FMCSA–2022–0036; FMCSA–2023–0021]

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 11 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 December 29, 2025.

ADDRESSES: You may submit comments identified by Docket No. FMCSA–2014–0102, FMCSA–2014–0107, FMCSA–2014–0385, FMCSA–2021–0015, FMCSA–2022–0034, FMCSA–2022–0035, FMCSA–2022–0036, or FMCSA–2023–0021, as appropriate, using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov, insert the docket number (FMCSA–2014–0102, FMCSA–2014–0107, FMCSA–2014–0385, FMCSA–2021–0015, FMCSA–2022–0034, FMCSA–2022–0035, FMCSA–2022–0036, or FMCSA–2023–0021) 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. Evangela Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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 (FMCSA–2014–0102, FMCSA–2014–0107, FMCSA–2014–0385, FMCSA–2021–0015, FMCSA–2022–0034, FMCSA–2022–0035, FMCSA–2022–0036, or FMCSA–2023–0021), 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–2014–0102, FMCSA–2014–0107, FMCSA–2014–0385, FMCSA–2021–0015, FMCSA–2022–0034, FMCSA–2022–0035, FMCSA–2022–0036, or FMCSA–2023–0021) 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. Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as "PROPIN" to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590-0001 or via email at brian.g.dahlin@dot.gov. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

C. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA-2014-0102, FMCSA-2014-0107, FMCSA-2014-0385, FMCSA-2021-0015, FMCSA-2022-0034, FMCSA-2022-0035, FMCSA-2022-0036, or FMCSA-2023-0021) 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.

D. 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, including any personal information the commenter provides, to

www.regulations.gov, as described in the system of records notice DOT/ALL-14 FDMS (Federal Docket Management System), which can be reviewed under the "Department Wide System of Records Notices" link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>.

The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

III. Background

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)).

The 11 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.

IV. 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.

V. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 11 applicants have satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 11 drivers in this notice remain in good standing with the Agency. In addition, the Agency has reviewed each applicant's certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Accordingly, 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 equivalent 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 August and are discussed below.

As of August 13, 2025, 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:

Frank Darracott (FL)
William Jones (MN)
David Presley (TX)
Christopher Shaw (MD)
Kirk Soneson (OH)
Joseph Stanford (OR)
Jeremy Stockman (KS)
Holly Wright (NC)

The drivers were included in docket number FMCSA–2014–0102, FMCSA–2014–0107, FMCSA–2014–0385, FMCSA–2021–0015, FMCSA–2022–0034, FMCSA–2022–0035, or FMCSA–2022–0036. Their exemptions were applicable as of August 13, 2025, and will expire on August 13, 2027.

As of August 16, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following three individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Dary Witczak Berke (MD); Esteban Castro (DE); and Alexander Gonzalez (FL). The drivers were included in docket number FMCSA–2023–0021. Their exemptions were applicable as of August 16, 2025, and will expire on August 16, 2027.

VI. Terms and Conditions

The exemptions are extended subject to the following conditions: each driver (1) must report to FMCSA any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391, within 7 days of the citation and conviction; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all the applicable commercial driver's license 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).

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 11 exemption renewal applications, FMCSA renews the exemptions of the above-named drivers from the hearing requirement in § 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21423 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0125; FMCSA–2014–0106; FMCSA–2014–0107; FMCSA–2014–0383; FMCSA–2015–0326; FMCSA–2018–0138; FMCSA–2023–0020]

Qualification of Drivers; Exemption Applications; Hearing

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 14 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.

FOR FURTHER INFORMATION CONTACT: Ms. Evangela Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA–2013–0125, FMCSA–2014–0106, FMCSA–2014–0107, FMCSA–2014–0383, FMCSA–2015–0326, FMCSA–2018–0138, or FMCSA–2023–0020) 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.

B. 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, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System), which can be reviewed under the “Department Wide System of Records Notices” link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely

achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

III. Background

On July 24, 2025, FMCSA published a notice announcing its decision to renew exemptions for 14 individuals from the hearing standard in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (90 FR 34958). The public comment period ended on August 25, 2025, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing, found in § 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)).

IV. Discussion of Comments

FMCSA received no comments in this proceeding.

V. Basis for Exemption Determination

The Agency's decision regarding these exemption applications is based on

relevant scientific information and literature, and the 2008 Evidence Report, "Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety."¹ The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) no studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver's license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant's certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is used as an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. Each applicant's record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equivalent or greater level of safety would likely be achieved by permitting each of these drivers to drive in interstate commerce, the Agency did not find any evidence that the drivers granted this exemption pose a risk to public safety.

Consequently, FMCSA further finds that in each case exempting these applicants from the hearing standard in § 391.41(b)(11) would likely achieve a level of safety equivalent to the level of safety that would be achieved without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

VI. Terms and Conditions

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: each driver (1) must report to FMCSA the date, location, and time of any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 within 7 days of the citations and convictions; (3) must

submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all applicable commercial driver's license testing requirements.

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 14 renewal exemption applications, FMCSA announces its decision to grant a 2-year exemption to each of the following drivers from the hearing requirement in § 391.41(b)(11).

As of June 17, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 12 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (90 FR 34958):

Jeremy Brandyberry (NE)
Kevin Ballard (TX)
Herbert Crowe (IN)
Mark Dickson (TX)
David Garland (ME)
Jacob Gadreault (MA)
Lane Grover (IN)
Paul Langlois (OH)
Sergio Miramontes (CA)
David Shores (NC)
James Thomason (MO)
Ramarr Wadley (PA)

The drivers were included in docket number FMCSA–2013–0125, FMCSA–2014–0106, FMCSA–2014–0107, FMCSA–2014–0383, FMCSA–2015–0326, or FMCSA–2018–0138. Their exemptions were applicable as of June 17, 2025, and will expire on June 17, 2027.

As of June 30, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Ryan Ketchner (TX); and Jerry Lacouture (TX).

The drivers were included in docket number FMCSA–2023–0020. Their exemptions were applicable as of June 30, 2025, and will expire on June 30, 2027.

¹ <https://www.fmcsa.dot.gov/regulations/medical/hearing-vestibular-function-and-commercial-motor-vehicle-driver-safety-executive>.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (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 prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21421 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2025–0024]

Qualification of Drivers; Exemption Applications; Hearing

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 11 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. The exemptions enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on August 30, 2025. The exemptions expire on August 30, 2027.

FOR FURTHER INFORMATION CONTACT: Ms. Evangela Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 527–4750, 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. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA–2025–0024) in the keyword box and click “Search.” Next, choose the only 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.

B. 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, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System), which can be reviewed under the “Department Wide System of Records Notices” link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant’s safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align

with the maximum duration of a driver’s medical certification.

III. Background

On July 24, 2025, FMCSA published a notice announcing receipt of applications from 11 individuals requesting an exemption from the hearing requirement in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (90 FR 34954). The public comment period ended on August 25, 2025, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing, found in § 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)).

IV. Discussion of Comments

FMCSA received no comments in this proceeding.

V. Basis for Exemption Determination

The Agency’s decision regarding these exemption applications is based on relevant scientific information and literature, and the 2008 Evidence Report, “Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety.”¹ The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) no studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver’s

¹ <https://www.fmcsa.dot.gov/regulations/medical/hearing-vestibular-function-and-commercial-motor-vehicle-driver-safety-executive>.

license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant's certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is used as an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. Each applicant's record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equivalent or greater level of safety would likely be achieved by permitting each of these drivers to drive in interstate commerce, the Agency did not find any evidence that the drivers granted this exemption pose a risk to public safety.

Consequently, FMCSA further finds that in each case exempting these applicants from the hearing standard in § 391.41(b)(11) would likely achieve a level of safety equivalent to the level of safety that would be achieved without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

VI. Terms and Conditions

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: each driver (1) must report to FMCSA the date, location, and time of any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 within 7 days of the citations and convictions; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all applicable commercial driver's license testing requirements.

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 11 exemption applications, FMCSA exempts the following drivers from the hearing standard in § 391.41(b)(11), subject to the requirements cited above:

Mark Abercrombie (SC)
Armando Bejarano (CA)
Charles Brubaker (VA)
Dimov Dimitar (CA)
Steven Hoyer (FL)
Andrew Love (MS)
Wanda Nivol (DE)
Antoine Parks (OH)
Juan Tenezaca (NJ)
Nicholas Walters (ND)
Chardena West (OH)

In accordance with 49 U.S.C. 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (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 prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025-21419 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2013-0124; FMCSA-2014-0102; FMCSA-2014-0104; FMCSA-2014-0106; FMCSA-2014-0107; FMCSA-2017-0061; FMCSA-2018-0138; FMCSA-2020-0027; FMCSA-2020-0028; FMCSA-2022-0034; FMCSA-2022-0038; FMCSA-2022-0039; FMCSA-2023-0017]

Qualification of Drivers; Exemption Applications; Hearing

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

ACTION: Notice of final disposition.

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.

FOR FURTHER INFORMATION CONTACT: Ms. Evangela Hollowell, Acting Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, (202) 527-4750, 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. Viewing Comments

To view comments, go to www.regulations.gov. Insert the docket number (FMCSA-2013-0124, FMCSA-2014-0102, FMCSA-2014-0104, FMCSA-2014-0106, FMCSA-2014-0107, FMCSA-2017-0061, FMCSA-2018-0138, FMCSA-2020-0027, FMCSA-2020-0028, FMCSA-2022-0034, FMCSA-2022-0038, FMCSA-2022-0039, or FMCSA-2023-0017, as appropriate) 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.

B. 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, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL-14 FDMS (Federal Docket Management System), which can be reviewed under the "Department Wide System of Records Notices" link at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted

without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)). FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

III. Background

On May 5, 2025, FMCSA published a notice announcing its decision to renew exemptions for 23 individuals from the hearing standard in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (90 FR 19077). The public comment period ended on June 4, 2025, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing, found in § 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)).

IV. Discussion of Comments

FMCSA received no comments in this proceeding.

V. Basis for Exemption Determination

The Agency's decision regarding these exemption applications is based on relevant scientific information and literature, and the 2008 Evidence Report, "Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety."¹ The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) no studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver's license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant's certified driving record from their State Driver's Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is used as an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. Each applicant's record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equivalent or greater level of safety would likely be achieved by permitting each of these drivers to drive in interstate commerce, the Agency did not find any evidence that the drivers granted this exemption pose a risk to public safety.

Consequently, FMCSA further finds that in each case exempting these

applicants from the hearing standard in § 391.41(b)(11) would likely achieve a level of safety equivalent to the level of safety that would be achieved without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

VI. Terms and Conditions

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: each driver (1) must report to FMCSA the date, location, and time of any crashes as defined in § 390.5T, within 7 days of the crash; (2) must report to FMCSA any citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 within 7 days of the citations and convictions; (3) must submit to FMCSA annual certified driving records from their SDLA; and (4) is 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 driver must meet all applicable commercial driver's license testing requirements.

VII. 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.

VIII. Conclusion

Based upon its evaluation of the 23 renewal exemption applications, FMCSA announces its decision to grant a 2-year exemption to each of the following drivers from the hearing requirement in § 391.41(b)(11).

As of March 3, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, the following 12 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Richard Blaine (PA)
John Darr (TN)
Scott Friede (TX)
Boris Garth (AL)
Jeremy Graslie (AZ)
Joshua Johnson (CO)
Timothy Lewey (TX)
Kimothy McLeod (GA)
Brett Ripp (FL)
Norlan Soler (NE)
Tony Walls (MD)

¹ <https://www.fmcsa.dot.gov/regulations/medical/hearing-vestibular-function-and-commercial-motor-vehicle-driver-safety-executive>.

Christopher Zrimsek (FL)

The drivers were included in docket number FMCSA–2014–0106, FMCSA–2017–0061, FMCSA–2018–0138, FMCSA–2020–0027, FMCSA–2020–0028, FMCSA–2022–0034, FMCSA–2022–0038, FMCSA–2022–0039, or FMCSA–2022–0049. Their exemptions were applicable as of March 3, 2025, and will expire on March 3, 2027.

As of March 10, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

David Helgerson (WI); and Susan Helgerson (WI).

The drivers were included in docket number FMCSA–2013–0124. Their exemptions were applicable as of March 10, 2025, and will expire on March 10, 2027.

As of March 13, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

John Huey (TX); and Scott Putman (TX).

The drivers were included in docket number FMCSA–2014–0107. Their exemptions were applicable as of March 13, 2025, and will expire on March 13, 2027.

As of March 19, 2025, and in accordance with 49 U.S.C. 31136(e) and 31315(b), and FMCSA's policy of issuing medical exemptions for a 2-year period to correspond with the medical certificate, Victor Morales (TX) has satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers.

This driver was included in docket number FMCSA–2014–0106. The exemption was applicable as of March 19, 2025, and will expire on March 19, 2027.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (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 prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2025–21430 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2025–0894]

Request for Comments on the Renewal of a Previously Approved Information Collection: Mariner Cadet Training-Agreements, Compliance Reporting, and Audits

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request approval from the Office of Management and Budget (OMB) to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0553 (Mariner Cadet Training-Agreements, Compliance Reporting, and Audits) is being updated to remove references to collection instrument placeholders that will no longer be implemented. Consequently, there is a decrease in the total public burden for this collection. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before January 27, 2026.

ADDRESSES: You may submit comments identified by Docket No. MARAD–2025–0894 through one of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. Search using the above DOT docket number and follow the online instructions for submitting comments.
 - **Mail or Hand Delivery:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.
- Instructions:** All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to

www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is reasonable for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be lessened without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT:

Jennifer Pralgo, 202–309–7187, Office of Cadet Training At-Sea Safety (MAR–660), Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, email: jennifer.pralgo@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Mariner Cadet Training-Agreements, Compliance Reporting, and Audits.

OMB Control Number: 2133–0553.

Type of Request: Extension of a currently approved collection.

Abstract: In accordance with its delegation of authority at 49 CFR 1.93(a), and pursuant to 46 U.S.C. 50101(a)(4), MARAD is charged with ensuring that the United States Merchant Marine is manned with trained and efficient citizen personnel. Furthermore, 46 U.S.C. 51322 requires MARAD to protect cadet mariners from sexual assault onboard vessels, establish sexual assault policy, and conduct random and targeted unannounced checks of commercial vessels. MARAD must obtain information from commercial vessel operators in order to meet its statutory objectives of setting sexual assault policy and monitoring compliance, which are essential to its mission of ensuring a well-trained U.S. Merchant Marine. MARAD uses information compiled through this collection to confirm acceptance of sexual assault policies by commercial vessel operators. This collection also establishes a process to oversee and monitor continued sexual assault policy compliance through reporting and auditing of commercial vessel operators, during initial enrollment and subsequent Sea Years.

Respondents: Commercial vessel operators employing United States Merchant Marine cadets onboard their vessels.

Affected Public: Individuals and households.

Estimated Number of Respondents: 75.

Estimated Number of Responses: 1.

Estimated Hours per Response: .25 to 6 hours.

Annual Estimated Total Annual Burden Hours: 108.75.

Frequency of Response: Once annually and/or following incident of a sexual assault or harassment.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administration.
T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.
 [FR Doc. 2025–21422 Filed 11–26–25; 8:45 am]
BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD–2025–0861]

Request for Comments on the Renewal of a Previously Approved Information Collection: Determination of Fair and Reasonable Rates for Carriage of Agriculture Cargoes on U.S.-Flag Commercial Vessels—46 CFR Part 382

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0514 (Determination of Fair and Reasonable Rates for Carriage of Agriculture Cargoes on U.S.-Flag Commercial Vessels—46 CFR Part 382) is used to determine fair and reasonable guideline rates for the carriage of preference cargoes on U.S.-flag commercial vessels. Since the last renewal, the public burden decreased due to fewer respondents. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before January 27, 2026.

ADDRESSES: You may submit comments identified by Docket No. MARAD–2025–0861 through one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Search using the above DOT docket number and follow the online instructions for submitting comments.

- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–

140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT:

Albert Bratton, 202–366–5769, Office of Business Finance, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: Albert.Bratton@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Determination of Fair and Reasonable Rates for Carriage of Agriculture Cargoes on U.S.-Flag Commercial Vessels—46 CFR Part 382.

OMB Control Number: 2133–0514.

Type of Request: Extension without change of a previously approved information collection.

Abstract: This collection requires U.S.-flag commercial vessel owners and operators to submit both operating and capital costs to MARAD annually.

Respondents: U.S. citizens who own and operate U.S.-flag vessels.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 22.

Estimated Number of Responses: 26.

Estimated Hours per Response: 1–10 hours.

Annual Estimated Total Annual Burden Hours: 134.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administration.
T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.
 [FR Doc. 2025–21427 Filed 11–26–25; 8:45 am]
BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2023–0047; Notice 2]

Michelin North America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Michelin North America, Inc. (MNA) has determined that certain Michelin LTX A/T2 tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires For Light Vehicles*. MNA filed an original noncompliance report dated April 14, 2023, and later amended the report on July 3, 2023. MNA subsequently petitioned NHTSA (the “Agency”) on April 17, 2023, and later amended the petition on July 6, 2023, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces the grant of MNA's petition.

FOR FURTHER INFORMATION CONTACT:

Jayton Lindley, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (325) 655–0547.

SUPPLEMENTARY INFORMATION:

I. Overview: MNA determined that certain Michelin LTX A/T2 tires size LT275/65R20 126/123R, do not fully comply with paragraphs S5.5(e) and S5.5(f) of FMVSS No. 139, *New Pneumatic Radial Tires For Light Vehicles* (49 CFR 571.139).

MNA filed an original noncompliance report dated April 14, 2023, and later amended the report on July 3, 2023, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. MNA petitioned NHTSA on April 17, 2023, and later amended the petition on July 6, 2023, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of MNA's petition was published with a 30-day public comment period, on March 26, 2024, in the **Federal Register** (89 FR 21170). No comments were received. To view the petition and all supporting documents log onto the Federal Docket

Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number “NHTSA–2023–0047.”

II. Tires Involved: Approximately 7,153 Michelin LTX A/T2 tires sized LT275/65R20 126/123R Load Range E, manufactured between January 15, 2023, and February 8, 2023, were reported by the manufacturer.

III. Noncompliance: MNA explains that the subject tires contain incorrect information regarding the general name of cord materials and the actual number of plies on the intended outboard sidewall of the tires, and therefore, do not fully comply with paragraphs S5.5(e) and S5.5(f) of FMVSS No. 139. Specifically, the sidewall of the subject tires states “TREAD PLIES: 2 POLYESTER + 2 STEEL SIDEWALL PLIES: 2 POLYESTER,” when they should state “TREAD PLIES: 2 POLYESTER + 1 POLYAMIDE + 2 STEEL SIDEWALL PLIES: 2 POLYESTER.”

IV. Rule Requirements: Paragraphs S5.5(e) and S5.5(f) of FMVSS No. 139 include the requirements relevant to this petition. Paragraph S5.5(e) requires that the sidewall be marked with the generic name of each cord material used in the plies (both sidewall and tread area) of the tire, and paragraph S5.5(f) requires that the sidewall be marked with the actual number of plies in the sidewall, and the actual number of plies in the tread area, if different.

V. Summary of MNA’s Petition: The following views and arguments presented in this section, “V. Summary of MNA’s Petition,” are the views and arguments provided by MNA. They do not reflect the views of the Agency. MNA describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

MNA explains that the subject noncompliance occurred as a result of an error made by a maintenance employee at the manufacturing site. On January 15, 2023, the employee accidentally used the incorrect plaque when replacing a loose one in a mold for the subject tire. A tire verification employee noticed a gap in the information in the tread plies plaque on the intended outboard side of the tire and notified the Quality team. MNA says that its internal investigation revealed that of the 7,997 tires produced, approximately 813 affected tires were identified and contained and approximately 598 affected tires (8 percent) of the production during this time period had entered the US market.

MNA asserts that the subject tires comply with all applicable FMVSS tire safety performance standards and they are marked with the correct tire size information, including the load range and maximum single and dual loads at the specified pressures. Further, MNA says that the subject tires were tested and passed all applicable FMVSS No. 139 performance tests. MNA says that it has taken corrective measures and removed the incorrect plaque from the mold used on the subject tires and replaced it with the correct plaque.

MNA contends that NHTSA has found petitions for similar noncompliances to be inconsequential to motor vehicle safety. MNA provides the following examples:

1. Michelin North America, Inc., NHTSA docket number 2020–0092, granted 7 February 2022.
2. Hankook Tire America Corporation, NHTSA docket number 2020–0020, granted 21 January 2022.
3. Continental Tire the Americas, LLC, NHTSA docket number 2017–0040, granted 30 July 2018.
4. Sumitomo Rubber Industries, Ltd., NHTSA docket number 2017–0071, granted 26 March 2018.
5. The Goodyear Tire and Rubber Company, NHTSA docket number 2016–0107, granted 17 April 2017.

MNA concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. NHTSA’s Analysis: In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.¹ In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will

¹ See *Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

not be safety issues in the future.² Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

NHTSA has evaluated the merits of the inconsequential noncompliance petition submitted by Michelin and agrees to grant the petitioner’s request for an exemption from the notification and remedy requirements of 49 U.S.C. 30118 and 49 U.S.C. 30120 based on the following:

NHTSA agrees that, based on the facts presented, this specific noncompliance of the subject tires is inconsequential to motor vehicle safety. The Agency considered the following prior to making this determination:

1. Operational Safety & Performance: NHTSA agrees that in this case, the missing marking for the polyamide tread ply on the tire has no effect on the operational safety of vehicle.

Additionally, the agency has no basis to believe that the affected tires do not meet all other performance and labeling requirements of the applicable FMVSS.

2. Tire Identification and Traceability: The tires have the required information per 49 CFR 574.5 to ensure that the tires may be properly registered for the purposes of a safety recall. The entire TIN, including the plant code and manufacturing date, is both legible and easily discernible.

3. Downstream Operations: The Agency must also consider other stakeholders, in addition to the manufacturer and end-user. Downstream entities involved in tire repair, retreading, and recycling operations require certain information to determine if tires may be safely used in their operations. The existence of steel in a tire’s sidewall and tread can be relevant to the manner in which it should be repaired or retreaded. The use of steel cord construction in the sidewall and tread is the primary safety concern of these industries. The Agency believes the noncompliance of the subject tires will have no measurable effect on the safety of the tire retread,

² See *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016); see also *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it “results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future”).

repair, and recycling industries since the tire sidewalls are marked correctly for the number of steel plies.

4. *Consumer Feedback and Focus Groups:* The Agency has concluded, based on previous feedback, that the tire construction information, specifically the number of plies and cord material in the sidewall and tread plies, influences very few consumers when they are deciding to buy a motor vehicle or replacement tires. This conclusion is based on information gathered from the Advance Notice of Proposed Rulemaking (ANPRM) that was published in the **Federal Register** on December 1, 2000, (65 FR 75222).

VII. *NHTSA's Decision:* In consideration of the foregoing, NHTSA finds that MNA has met its burden of persuasion that the subject FMVSS No. 139 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, MNA's petition is hereby granted and MNA is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that MNA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after MNA notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025-21527 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket Nos. NHTSA-2021-0056, NHTSA-2021-0057; Notice 2]

Vee Rubber Corporation Ltd. and American Honda Motor Co., Inc., Grant of Petitions for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petitions.

SUMMARY: Vee Rubber Corporation Ltd. (VRC) and American Honda Motor Co., Inc., (Honda) have determined that certain Vee Rubber VRM133 motorcycle tires sold as replacement equipment and as original equipment for installation on certain model year (MY) 2019–2021 Honda Monkey motorcycles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 Kilograms (10,000 Pounds), Specialty Tires, and Tires for Motorcycles*. VRC filed a noncompliance report dated June 7, 2021, and Honda filed a noncompliance report dated June 22, 2021. Subsequently, VRC petitioned NHTSA on June 22, 2021, and Honda petitioned NHTSA on July 14, 2021, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces the grant of VRC and Honda's petitions.

FOR FURTHER INFORMATION CONTACT: Jayton Lindley, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (325) 655-0547.

SUPPLEMENTARY INFORMATION:

I. *Overview:* VRC and Honda have determined that certain Vee Rubber VRM133 motorcycle tires sold as replacement equipment and as original equipment for installation on certain 2019–2021 Honda Monkey motorcycles do not fully comply with the requirements of paragraph S6.5(b) of FMVSS No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 Kilograms (10,000 Pounds), Specialty Tires, and Tires for Motorcycles* (49 CFR 571.119).

VRC filed a noncompliance report dated June 7, 2021, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. VRC subsequently petitioned NHTSA on June 22, 2021, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor

vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Honda filed a noncompliance report dated June 22, 2021, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. Honda subsequently petitioned NHTSA on July 14, 2021, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of VRC and Honda's petitions was published with a 30-day public comment period in the **Federal Register** (87 FR 79440, December 27, 2022). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number "NHTSA-2021-0056."

II. *Tires Involved:* Approximately 29,018 Vee Rubber VRM133 motorcycle tires sizes 120/80–12 and 130/80–12, sold as original equipment to Honda for installation in certain Honda motorcycles, and manufactured between March 5, 2018, and May 27, 2021, are potentially involved.

The subject tires were installed as original equipment on approximately 13,328 MY 2019–2021 Honda Monkey motorcycles manufactured between July 4, 2018, and April 2, 2021, and therefore these vehicles are also potentially involved.

III. *Noncompliance:* VRC and Honda explain that the noncompliance is that the subject tires contain extra markings between the manufacturer's code and production week mark within the tire identification number (TIN), and, therefore, do not comply with the requirements specified in paragraph S6.5(b) of FMVSS No. 119. Specifically, the tires included an extra grouping of characters, beginning with the letter "V" followed by numbers between the second and third grouping of characters. For example, the tires were marked "DOT 15A BCN133 Vxxxxxx xxxx" or "DOT 15A BBN133 Vxxxxxx xxxx" when they should have been marked "DOT 15A BCN133 xxxx" or "DOT 15A BBN133 xxxx," with "x" representing the number present on a specific tire.

IV. *Rule Requirements:* Paragraph S6.5(b) of FMVSS No. 119 includes the requirements relevant to these petitions. S6.5(b) provides that the TIN must meet

the requirements as stated in 49 CFR 574 and may be marked on only one sidewall. 49 CFR 574.5(a) requires, in relevant part, that each new tire manufacturer must conspicuously label on one sidewall of each tire it manufactures, by permanently molding into or onto the sidewall, a TIN consisting of 13 symbols that contains the plant code, manufacturer's code, and date code, as described in paragraphs (b)(1) through (b)(3) of 49 CFR 574.5.

V. Summary of VRC and Honda's Petitions: The following views and arguments presented in this section, "V. Summary of VRC and Honda's Petitions," are the views and arguments provided by VRC and Honda. They do not reflect the views of the Agency. VRC and Honda describe the subject noncompliance and contend that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of their petitions, VRC and Honda submitted the following reasoning:

VRC claims that the subject tires meet the performance requirements of FMVSS No. 119 and, therefore, the "markings have no impact on the operational performance of the tires or on the safety of motorcycles on which these tires are installed." VRC also claims that the subject tires contain "a complete and identifiable TIN which is accessible while mounted" and that in the event of a recall, a consumer would have access to all the necessary information required to determine whether their tires are subject to a recall.

In Honda's petition, they state that they support VRC's petition and believe that the extra markings on the tires do not pose a safety risk to riders or affect the performance of the subject motorcycle tires. Honda added that the subject tires are both identifiable and traceable since the extra markings "do not alter or remove any required identifying characters of the TIN."

The petitioners referred to the following inconsequential noncompliance petitions granted by NHTSA that they believe support the granting of their petitions for the subject noncompliance:

- Michelin North America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance; 85 FR 37495, June 22, 2020.
- Bridgestone Firestone North America Tire, LLC, Grant of Petition for Decision of Inconsequential Noncompliance; 71 FR 4396, January 26, 2006.
- Cooper Tire & Rubber Company, Grant of Petition for Decision of

Inconsequential Noncompliance; 71 FR 4396, January 26, 2006.

- Cooper Tire & Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance; 82 FR 17075, April 7, 2017.

- Nitto Tire USA., Inc., Grant of Petition for Decision of Inconsequential Noncompliance; 81 FR 17764, March 30, 2016.

- Hankook Tire America, Grant of Petition for Decision of Inconsequential Noncompliance; 79 FR 30688, May 28, 2014.

The petitioners state that they are not aware of any customer claims, complaints, injuries, incidents, or field reports associated with the extra markings in the TIN on the affected tires.

VRC states that they have already corrected the error at its plant so that the TIN on all new Model VRM133 tires in the affected sizes will be marked according to S6.5(b) of FMVSS No. 119. VRC also states that they have recovered all affected tires in possession of United States distributors or retailers that have not yet reached end-users.

The petitioners conclude their petitions by contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety and that their petitions to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. NHTSA's Analysis: In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.¹ In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.²

¹ See *Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

² See *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016); see also *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect

Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

NHTSA has evaluated the merits of the inconsequential noncompliance petition submitted by VRC and Honda and agrees to grant the petitioner's request for an exemption from the notification and remedy requirements of 49 U.S.C. 30118 and 49 U.S.C. 30120 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety. The Agency considered the following prior to making this determination:

NHTSA has no basis to believe that the tires do not otherwise meet the performance and labeling requirements of FMVSS No. 119 based on information provided by the manufacturer.

In addition, NHTSA agrees that the additional characters in the TIN do not affect the ability of the manufacturer to identify the affected tires in the event of a recall in this specific case. The agency has confirmed with the manufacturer that all the subject tires were sent directly to Honda as original equipment on new motorcycles. Honda replaced and scrapped all the noncompliant tires that were within their inventory. For the vehicles that were sold with noncompliant tires, a consumer would register the vehicle and be notified by Honda in the event of a future recall. The petitioners argue that the TIN is identifiable and the extra markings do not alter the required TIN content. The agency is not persuaded by this argument because we disagree with this characterization since the additional characters are inserted into the middle of the TIN. However, because these tires are only sold as original equipment, any future safety recall would be completed by notifying consumers based on the VIN of the vehicle rather than the TIN markings of the tires.

VRC cited numerous petitions that have been granted in the past for various labeling noncompliances. Of those cited, the agency believes that only one is related to the subject noncompliance. The Michelin North America petition cited (85 FR 37495) involves the symbol "DOT" being mistakenly placed within the TIN thus creating a TIN with

poses an unreasonable risk when it "results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future").

additional characters. The agency granted this petition based on the fact that the symbol “DOT” is correctly marked on one sidewall of the tire and that the manufacturer communicated that the tires will still be able to be registered. Therefore, while it may be relevant in some aspects, the number and nature of the incorrect symbols inserted into the TIN are sufficiently different when compared to the subject petition and NHTSA does not find the rationale in the Michelin grant persuasive in this instance.

Unlike the subject petition, in cases where the tires are not sold as original equipment on vehicles, TIN errors like this noncompliance potentially impact the consumer’s ability to successfully register their tires. Despite NHTSA’s decision to grant this petition, the agency remains concerned that TIN errors such as the one found here frustrate the tire registration process when not sold as original equipment on vehicles, and have the potential to negatively impact recall effectiveness in general. Because these TIN errors also violate 49 CFR part 574, it is possible for NHTSA to seek civil penalties for violations of these requirements, and NHTSA may consider doing so if violations potentially affect the ability to recall tires.

VII. NHTSA’s Decision: In consideration of the foregoing, NHTSA finds that VRC and Honda have met their burden of persuasion that the subject FMVSS No. 119 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, VRC and Honda’s petitions are hereby granted and VRC and Honda are consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires and vehicles that the petitioners no longer controlled at the time it determined that the noncompliance existed. However, the grant of these petitions does not relieve tire and vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of

the noncompliant tires and vehicles under their control after VRC and Honda notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025–21525 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2023–0004; Notice 2]

Michelin North America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Michelin North America, Inc. (MNA) has determined that certain Michelin X Works D tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 kilograms (10,000) pounds, Speciality Tires, and Tires for Motorcycles*. MNA filed a noncompliance report dated December 16, 2022, and January 11, 2023, and subsequently petitioned NHTSA on January 10, 2023, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces the grant of MNA’s petition.

FOR FURTHER INFORMATION CONTACT:

Jayton Lindley, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (325) 655–0547.

SUPPLEMENTARY INFORMATION:

I. Overview: MNA determined that certain Michelin X Works D tires do not fully comply with paragraph S6.5(d) of FMVSS No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 kilograms (10,000) pounds, Speciality Tires, and Tires for Motorcycles* (49 CFR 571.119).

MNA filed a noncompliance report dated December 16, 2022, and amended the report on January 11, 2023, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. MNA petitioned NHTSA on January 10, 2023, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is

inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of MNA’s petition was published with a 30-day public comment period, on March 29, 2024, in the **Federal Register** (89 FR 22228). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number “NHTSA–2023–0004.”

II. Tires Involved: Approximately 14,047 Michelin X Works D tires, manufactured between January 1, 2021, and September 14, 2022, were reported by the manufacturer.

III. Rule Requirements: Paragraph S6.5(d) of FMVSS No. 119, includes the requirements relevant to this petition. Except as specified in paragraph S6.5, each tire must be marked on each sidewall with the information specified in paragraphs (a) through (j) of paragraph S6.5.

IV. Noncompliance: MNA explains that the noncompliance is that the maximum dual load in pounds is incorrectly marked on both sides of the tire and therefore does not comply with paragraph S6.5 (d) of FMVSS No. 119. Specifically, the tires state the maximum dual load as 5,590 pounds at 120 psi, when they should state 6,005 pounds at 120 psi.

V. Summary of MNA’s Petition: The following views and arguments presented in this section, “V. Summary of MNA’s Petition,” are the views and arguments provided by MNA. They do not reflect the views of NHTSA. MNA describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

MNA explains that the subject noncompliance was detected during a review of markings for this tire line. MNA says that the mold drawings were corrected for future production upon detection of the subject noncompliance. MNA’s investigation of the affected tires concluded that all tires produced with the marking error had entered the market.

First, MNA states that the subject tires were designed and manufactured in accordance with Tire and Rim Association standards, which specify a single max load of 3,000 kg (6,610 lbs) and a dual max load of 2,725 kg (6,005 lbs), both at an inflation pressure of 830 kPa (120 psi). Further, MNA asserts that the subject tires fully comply with all

applicable FMVSS tire safety performance standards. MNA highlights that paragraph S7.2(a) of FMVSS No. 119 provides that endurance testing is conducted at the maximum single load value when the tire is marked with both single and dual maximum loads. MNA notes that the correct single load values in kilograms and pounds are marked on the tire. Further, MNA states that except for the max dual load marking in pounds on both sides of the tire, the affected tires correctly display all other required regulatory markings, including load range H corresponding to the designed maximum single load of 3,000 kilograms or 6,610 pounds, the maximum dual load of 2,725 kilograms, as well as the correct inflation pressure of 830 kPa or 120 psi.

MNA explains that these markings provide both dealers and fleets with the necessary information to enable proper selection and application of the tires. MNA says that if a dealer or fleet were to follow the erroneous maximum dual load in pounds marked on the subject tires, the resulting tire loading would be 55 pounds below the designed maximum dual load of this tire.

MNA states that it has taken corrective measures in production and all tires currently being produced have the correct marking.

MNA refers to the following NHTSA petition decisions that it contends are similar to the subject noncompliance:

- Michelin North America, Inc., docket number NHTSA–2006–25891, granted 22 December 2006.
- Goodyear Tire and Rubber Company, docket number NHTSA–2005–21269, granted 18 July 2005.

MNA concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. NHTSA's Analysis: In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.¹ In general, NHTSA

does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.² Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

NHTSA has evaluated the merits of the inconsequential noncompliance petition submitted by Michelin and agrees to grant the petitioner's request for an exemption from the notification and remedy requirements of 49 U.S.C. 30118 and 49 U.S.C. 30120 based on the following:

The tires that are the subject of this petition are designed and manufactured to have a higher maximum load than the erroneous value in pounds that is marked on the sidewall for a dual configuration. Because of this, consumers who follow those marked load values in pounds will not be in danger of overloading the tires. NHTSA has no basis to believe that the tires are not compliant with all other requirements of FMVSS No. 119.

VII. NHTSA's Decision: In consideration of the foregoing, NHTSA finds that MNA has met its burden of persuasion that the subject FMVSS No. 119 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, MNA's petition is hereby granted and MNA is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or

noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that MNA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after MNA notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025–21529 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0024; Notice 1]

ST Engineering Hackney, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: ST Engineering Hackney, Inc., (STE Hackney), has determined that certain model year (MY) 2015–2022 Kidron Refrigerated Van trailers do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 223, *Rear Impact Guards*. On January 28, 2022, STE Hackney filed an original noncompliance report and amended the report on February 28, 2022, April 16, 2024, and April 17, 2024. STE Hackney petitioned NHTSA on February 28, 2022, and amended the petition on April 16, 2024, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces receipt of STE Hackney's petition.

DATES: Send comments on or before December 29, 2025.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and may be submitted by any of the following methods:

- **Mail:** Send comments by mail addressed to the U.S. Department of

¹ See *Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

² See *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016); see also *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it “results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future”).

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.

- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Follow the online instructions for submitting comments.

- Comments may also be faxed to (202) 493-2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at <https://www.regulations.gov/> by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477-78).

FOR FURTHER INFORMATION CONTACT: Corey Barlet, General Engineer, NHTSA,

Office of Vehicle Safety Compliance, (202) 366-1119.

SUPPLEMENTARY INFORMATION:

I. Overview: STE Hackney determined that certain MY 2015–2022 Kidron Refrigerated Van trailers it manufactures do not fully comply with paragraph S5.3(a) of FMVSS No. 223, *Rear Impact Guards* (49 CFR 571.223).

On January 28, 2022, STE Hackney filed an original noncompliance report and amended the report on February 28, 2022, April 16, 2024, and April 17, 2024, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. STE Hackney petitioned NHTSA on February 28, 2022, and amended its petition on April 16, 2024, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

This notice of receipt of STE Hackney's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or another exercise of judgment concerning the merits of the petition.

II. Vehicles Involved: Approximately 2,428 MY 2015–2022, Kidron Refrigerated Van trailers manufactured between November 3, 2014, and January 24, 2022, were reported by the manufacturer.

III. Noncompliance: STE Hackney explains that rear impact guard labels on the subject trailers did not include the guard manufacturer's address, as required by paragraph S5.3(a) of FMVSS No. 223.

IV. Rule Requirements: Paragraph S5.3(a) of FMVSS No. 223 includes the requirements relevant to this petition. Each guard is required to be permanently labeled with certain information including the guard manufacturer's address.

V. Summary of STE Hackney's Petition: The following views and arguments presented in this section, "V. Summary of STE Hackney's Petition," are the views and arguments provided by STE Hackney. They have not been evaluated by the Agency and do not reflect the views of the Agency. STE Hackney describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

STE Hackney explains that the rear impact guard label on the subject trailers is placed in the correct position

and contains the manufacturer's name, production date, and "DOT" certification marking as required by FMVSS No. 223 paragraph S5.3. While the manufacturer's address is not included on the rear impact guard label as required by S5.3(a) of FMVSS No. 223, STE Hackney says that the missing manufacturer's address can be found on the manufacturer's certification label that is affixed on every trailer that STE Hackney manufactures.

STE Hackney states that it "can certify that each vehicle was produced with compliant rear impact guard manufactured and installed by STE Hackney." Furthermore, STE Hackney was contacted by a customer requesting replacement labels, and says that "in the long period that these units have been in service, they have only recently been given notice that the manufacturer address was omitted on the rear guard."

STE Hackney concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that STE Hackney no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after STE Hackney notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025-21524 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION**National Highway Traffic Safety Administration****[Docket No. NHTSA–2021–0076; Notice 2]****Continental Tire the Americas, LLC, Grant of Petition for Decision of Inconsequential Noncompliance****AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).**ACTION:** Grant of petition.

SUMMARY: Continental Tire the Americas, LLC (“CTA”), has determined that certain Continental Nanocontact A/S tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles*. CTA filed an original noncompliance report dated September 10, 2021, and subsequently petitioned NHTSA on September 30, 2021, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces the grant of CTA’s petition.

FOR FURTHER INFORMATION CONTACT: Jayton Lindley, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (325) 655–0547.

SUPPLEMENTARY INFORMATION:**I. Overview**

CTA has determined that certain Continental VanContact A/S tires do not fully comply with the requirements of paragraph S5.5(b) of FMVSS No. 139, *New Pneumatic Radial Tires for Light Vehicles* (49 CFR 571.139). CTA filed a noncompliance report dated September 10, 2021, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. CTA subsequently petitioned NHTSA on September 30, 2021, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of CTA’s petition was published with a 30-day public comment period, on April 18, 2024, in the **Federal Register** (89 FR 27831). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number “NHTSA–2021–0076.”

II. Tires Involved

Approximately 419 Continental VanContact A/S tires, size LT245/70R17 119/116 Q, manufactured between May 31, 2020, and May 22, 2021, are potentially involved.

III. Noncompliance

CTA explains that the noncompliance is that the tire size designation on both sidewalls of the subject tires, is missing the tire size prefix “LT” and, therefore, does not fully comply with paragraph S5.5(b) of FMVSS No. 139. Specifically, the tire size on the subject tires’ sidewalls read “245/70R17 119/116 Q,” however, they should read “LT245/70R17 119/116 Q.”

IV. Rule Requirements

Paragraph S5.5(b) of FMVSS No. 139 includes the requirements relevant to this petition. Each tire must be marked on each sidewall with the tire size designation as listed in the documents and publications specified in S4.1.1 of the standard.

V. Summary of CTA’s Petition

The following views and arguments presented in this section, “V. Summary of CTA’s Petition,” are the views and arguments provided by CTA. They do not reflect the views of NHTSA. CTA describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, CTA submits the following reasoning:

CTA says that other than the missing tire size designation marking on both sidewalls, the subject tires contain all other required markings and meet all the performance requirements of FMVSS 139 for LT 245/70R17 119/116 Q, Load Range E tires.

CTA states its belief that the missing markings do not impact the operational safety of the tires. CTA adds that the subject tire sidewalls contain the correct markings for the Load Index and load capacities for single and dual fitments and that “there is no higher load tire specified for size 245/70R17 in the [Tire and Rim Association] yearbook or the European Tyre and Rim Technical Organization, thus the tires could not mistakenly be placed in an overloaded application.”

CTA contends that the granting of a petition submitted by Michelin North America Incorporated describes a similar noncompliance to the one affecting the subject tires and therefore, supports the granting of its petition. See Michelin North America, Incorporated, Grant of Petition for Decision of

Inconsequential Noncompliance, 78 FR 30963 (May 23, 2013).

CTA also says that the subject tires were installed on “pre-serial production vehicles” that were not sold to end consumers or released into the replacement tire market. Additionally, CTA says that all remaining CTA inventory will be scrapped and that “no additional tires will be manufactured or sold with the noncompliance.”

CTA concludes that the subject noncompliance is inconsequential as it relates to motor vehicle safety and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

In response to email correspondence from NHTSA on November 7, 2022, CTA clarified that Rivian owned, controlled, and operated the subject vehicles and the tires were sent to Toyota Arizona Proving Grounds for Prototype vehicle testing.

VI. NHTSA’s Analysis

In determining the inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.¹ In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.² Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that

¹ See *Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

² See *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016); see also *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it “results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future”).

they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

NHTSA has evaluated the merits of the petition submitted by CTA and is granting its request for relief from notification and remedy based on the following:

1. NHTSA has no basis to believe that the subject tires do not meet the performance and labeling requirements of FMVSS No. 139, except for the “LT” size designation marking.

2. CTA has confirmed that all the subject tires were installed on pre-serial production vehicles which will not be sold to consumers, and consequently, none of the subject tires were sold into the replacement market. Because of this, the risk of the tires being incorrectly applied to a vehicle for which they were not designed is minimized.

3. All the tire loading information, including the load range letter “E,” is correctly marked. Therefore, omission of the LT designation combined with the fact that the subject tires are correctly marked with the highest load specified for 245/70R17 tires within the TRA Yearbook and ETRTO manuals, does not increase risk of overloading the tires, regardless of the vehicle on which the tires are installed.

VII. NHTSA’s Decision

In consideration of the foregoing, NHTSA finds that CTA has met its burden of persuasion that the subject FMVSS No. 139 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, CTA’s petition is hereby granted and CTA is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that CTA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their

control after CTA notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke, III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025–21526 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0040; Notice 2]

Michelin North America Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Michelin North America, Inc., (MNA), has determined that certain Michelin X Multi D+ replacement tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 kilograms (10,000 pounds), Specialty Tires, and Tires for Motorcycles*. MNA filed an original noncompliance report dated March 25, 2022. MNA subsequently petitioned NHTSA on April 19, 2022, and later supplemented the petition on September 20, 2022, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces the grant of MNA’s petition.

FOR FURTHER INFORMATION CONTACT: Jayton Lindley, Office of Vehicle Safety Compliance, NHTSA, (325) 655–0547.

SUPPLEMENTARY INFORMATION:

I. Overview: MNA determined that certain Michelin X Multi D+ replacement tires do not fully comply with paragraph S6.5(j) of FMVSS No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 kilograms (10,000 pounds), Specialty Tires, and Tires for Motorcycles*. (49 CFR 571.119).

MNA filed an original noncompliance report dated March 25, 2022, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. MNA subsequently petitioned NHTSA on April 19, 2022, and later supplemented the petition on September 20, 2022, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301

on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of MNA’s petition was published with a 30-day public comment period, on July 12, 2022, in the **Federal Register** (87 FR 41380). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number “NHTSA–2022–0040.”

II. Tires Involved: Approximately 160 Michelin X Multi D+, size 11R22.5, replacement tires, manufactured between May 26, 2019, and June 29, 2019, were reported by the manufacturer.

III. Noncompliance: MNA explains that the noncompliance was due to a mold error in which the subject tires are missing the letter designating the tire load range as required by paragraph S6.5(j) of FMVSS No. 119. Specifically, the sidewalls of the subject tires omit the designated load range letter “H.”

IV. Rule Requirements: Paragraph S6.5(j) of FMVSS No. 119 includes the requirements relevant to this petition. The subject tires are required to be marked on each sidewall with the tire load range letter.

V. Summary of MNA’s Petition: The following views and arguments presented in this section, “V. Summary of MNA’s Petition,” are the views and arguments provided by MNA and do not reflect the views of the Agency. MNA describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

MNA explains that the noncompliance was found when a Michelin Field Engineer was notified that some of the subject tires “had a different tread pattern than the customer was accustomed to.” MNA explains that the subject tires were intended for the Asia and India tire markets, yet “entered the U.S. through channels outside of Michelin’s control.” MNA states that the tires were certified to the applicable U.S. FMVSS, and properly labeled with the certification symbol “DOT” despite being manufactured for markets other than the U.S. MNA also states that it has taken corrective measures to block the SKUs in its internal databases to prevent shipment and sale through MNA’s distribution channels.

MNA states that the subject tires were manufactured as a load index 148

single/145 dual tire with a maximum single load rating of 3,150 kilograms or 6,940 pounds at 830 kPa or 120 psi cold inflation pressure and a maximum dual load rating of 2,900 kilograms or 6,395 pounds at 830 kPa or 120 psi cold inflation pressure. MNA asserts that it tested the subject tires and found that they comply with the necessary performance requirements required by FMVSS No. 119. Except for the subject noncompliance, MNA also claims that the subject tires meet all marking requirements and “are also marked with load indices for single and dual applications,” which MNA contends will “provide both dealers and consumers with the necessary information to enable proper selection and application of the tires.” MNA also states that the molds will be updated to include the required load range letter designation and until then, the SKU will remain blocked in its systems.

MNA says that NHTSA has previously granted petitions which it believes are similar to the subject petition. MNA refers to the granting of the petition submitted by China Manufacturers Alliance, LLC (79 FR 78562), for truck and bus radial replacement tires that were missing the load range letter.

MNA concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

On September 20, 2022, MNA supplemented its petition with evidence that it relied on to certify that the tires comply with the performance requirements of FMVSS No. 119.

VI. NHTSA's Analysis: In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.¹ In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle

occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.² Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

NHTSA has evaluated the merits of the inconsequential noncompliance petition submitted by MNA and is granting MNA's request for relief from notification and remedy based on the following:

1. Based on information submitted by MNA, NHTSA has no clear basis to determine that the tires do not meet all performance requirements of FMVSS No. 119, including the applicable static breaking energy requirement for a load range “H” tire.

2. The Agency agrees that information intended to be conveyed by the missing load range letter is contained in the other markings on the tires, specifically: the maximum load and maximum permissible inflation pressures that are marked on the sidewall of the subject tires. The marked values correctly correlate to the maximum loads and pressure listed by the ETRTO 2019 yearbook. The Agency believes that enough information is present on the subject tires for both dealers and consumers to properly select and use the tires.

3. NHTSA believes that the missing load range letter will not affect the ability of the manufacturer or consumer to identify the affected tires in the event of a recall.

VII. NHTSA's Decision: In consideration of the foregoing, NHTSA finds that MNA has met its burden of persuasion that the subject FMVSS No. 119 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, MNA's petition is hereby granted and MNA is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that MNA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after MNA notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke, III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025–21528 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2023–0049; Notice 1]

Ford Motor Company, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Ford Motor Company (Ford) has determined that certain model year (MY) 2021–2023 Ford and Lincoln motor vehicles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 138, *Tire Pressure Monitoring Systems*, and FMVSS No. 209, *Seat Belt Assemblies*. Ford filed a noncompliance report dated June 9, 2023, and subsequently petitioned NHTSA (the “Agency”) on June 29, 2023, for a decision that the subject noncompliances are inconsequential as they relate to motor vehicle safety. This document announces receipt of Ford's petition.

DATES: Send comments on or before December 29, 2025.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition.

¹ See *Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

² See *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016); see also *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it “results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future”).

Comments must refer to the docket and notice number cited in the title of this notice and may be submitted by any of the following methods:

- **Mail:** Send comments by mail addressed to the 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 comments by hand to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.

- **Electronically:** Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Follow the online instructions for submitting comments.

- Comments may also be faxed to (202) 493-2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at <https://www.regulations.gov/> by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477-78).

FOR FURTHER INFORMATION CONTACT:

Kamna Ralhan, General Engineer, NHTSA, OVSC, (202) 366-6443 or Kelley Adams-Campos, Safety Compliance Engineer, NHTSA, Office of Vehicle Safety Compliance (OVSC), (202) 366-7479.

SUPPLEMENTARY INFORMATION:

I. **Overview:** Ford determined that certain MY 2021-2023 Ford and Lincoln motor vehicles do not fully comply with paragraph S4.5(a) of FMVSS No. 138, *Tire Pressure Monitoring Systems*, (49 CFR 571.138) and paragraph S4.1(l) of FMVSS No. 209, *Seat Belt Assemblies* (49 CFR 571.209).

Ford filed a noncompliance report dated June 9, 2023, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. Ford petitioned NHTSA on June 29, 2023, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

This notice of receipt of Ford's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or another exercise of judgment concerning the merits of the petition.

II. **Vehicles Involved:** Approximately 1,876,448 of the following Ford and Lincoln motor vehicles, manufactured between January 8, 2020, and May 30, 2023, were reported by the manufacturer:

- MY 2021-2023 Ford F-150
- MY 2021-2023 Ford Mustang Mach-E
- MY 2021-2023 Ford Bronco
- MY 2021-2023 Ford Edge
- MY 2022-2023 Ford Expedition
- MY 2023 Ford F-Super Duty: F-250, F-350, F450, F-550, F-600
- MY 2023 Ford Escape
- MY 2021-2023 Lincoln Nautilus
- MY 2022-2023 Lincoln Navigator
- MY 2023 Lincoln Corsair

III. **Rule Requirements:** Paragraphs S4.5(a) of FMVSS No. 138 and paragraph S4.1(l) of FMVSS No. 209 include the requirements relevant to this petition. Paragraph S4.5(a) of FMVSS No. 138 requires that the owner's manual provided with each vehicle certified as complying with paragraph S4 of FMVSS No.138 must include the statement specified in paragraph S4.5(a), which details the

importance of maintaining proper tire pressure and explains the functionality of the tire pressure monitoring system (TPMS). Paragraph S4.1(l) of FMVSS No. 209 requires, in part, that a seat belt assembly include written instructions on the proper use, maintenance and periodic inspection of the seatbelt assembly and related components.

IV. **Noncompliance:** Ford explains that the printed paper document provided with the subject vehicles is missing certain information that is required by FMVSS Nos. 138 and 209. Specifically, the document is missing the statement required by paragraph No. 4.5(a) of FMVSS No. 138, which provides information about the TPMS, and the written instructions required by S4.1(l) of FMVSS No. 209 regarding the maintenance and periodic inspection of the seatbelt assembly and related components.

V. **Summary of Ford's Petition:** The following views and arguments presented in this section, "V. Summary of Ford's Petition," are the views and arguments provided by Ford. They have not been evaluated by the Agency and do not reflect the views of the Agency. Ford describes the subject noncompliances and contends that the noncompliances are inconsequential as they relate to motor vehicle safety.

Ford explains that it introduced Digital Owner's Manuals (DOM) into U.S. vehicles starting with the MY 2021 Ford F-150 and Ford Mustang Mach-E motor vehicles, and DOMs have since been phased into the other subject vehicles. Ford notes that customers who purchase vehicles equipped with a DOM also receive a Supplemental Owner's Guide (SOG), a printed paper document that contains a subset of information available in the DOM. Prior to the introduction of the DOM, Ford determined that certain information was required to be provided to customers in printed form to comply with FMVSS requirements. Ford states that its intent was to provide printed information to customers in the SOG.

On May 11, 2023, Ford's Critical Concern Review Group (CCRG) reviewed an issue involving missing content from the SOG. The investigation found that information required by FMVSS Nos. 138 and 209 to be provided in the owner's manual or in writing was missing from the SOG. However, Ford states that the CCRG also found that the required information was included in the DOM for the subject vehicles.¹

¹ Ford notes that 26,957 MY 2022 Ford Mustang Mach-E motor vehicles lost access to the DOM after an over the air (OTA) software update in January 2023 unintentionally deleted it. As of May 23, 2023,

Ford references a May 18, 2009, interpretation by NHTSA's Chief Counsel's Office, which states that certain FMVSSs require information to be provided in written form, either in owner's manuals if one is provided, or in a paper format. Ford notes that the interpretation also specifies the advantages of hard copy owner's manuals.² In 2021, NHTSA published a notice in the **Federal Register** soliciting comments on the paperwork burdens associated with vehicle owner's manual requirements and received a comment from Alliance for Automotive Innovation suggesting that NHTSA reduce the paperwork burden of printing and distributing written owner's manuals by interpreting the requirements to permit digital format owner's manuals as an alternative to printed copies. Ford says that NHTSA responded that no such compliance option currently exists for digital formats, and the Auto Innovators' request to change the FMVSS is outside of the scope of the reinstatement request, though NHTSA would consider the request for future Agency action.³

Ford cites Maserati North America's (MNA) 2020 petition for a determination of inconsequential noncompliance, which involved a similar noncompliance regarding digital owner's manuals accessible through the vehicle's touchscreen.⁴

Regarding the subject noncompliance, Ford explains that while the language required by paragraph S4.5(a) of FMVSS No. 138 is not included in the printed SOG provided with the vehicle, it is provided to customers digitally in the DOM. Similarly, for FMVSS No. 209, Ford states that although the printed SOG does not include the written instructions on the maintenance and periodic inspection of the seatbelt assembly and related components, these instructions were included in the DOM.

Ford contends that the subject noncompliance is inconsequential to motor vehicle safety because vehicle

occupants can access all required owner's manual content, including the information required by FMVSS No. 138 and FMVSS No. 209, through the DOM displayed on the center console's infotainment screen. Ford asserts that the DOM is organized with a table of contents and a search function, allowing users to easily locate information. Ford emphasizes that, unlike the compact disc (CD) manual referenced in a NHTSA 2009 interpretation, the DOM is integrated into the vehicle and, therefore, cannot be misplaced.⁵ Appendix I of Ford's petition details the steps for accessing the DOM through the infotainment screen, with similar steps applicable to all affected vehicles.

Ford also states that the required owner's manual information is available to the public via ford.com/supportandlincoln.com/support, and vehicle owners can access it through the "Ford Pass" and "Lincoln Way" mobile applications. According to Ford, the owner's manual for all affected vehicles is available online, along with informational videos about the vehicles. The online owner's manual includes the information required by paragraph S4.5 of FMVSS No. 138, and the written information required by paragraph S4.1(l) of FMVSS No. 209. Ford states that the owner's manuals are accessible by vehicle identification number or by model year and model lookup. Additionally, the Ford website address is provided in the "Introduction" section of the affected vehicles' SOG.

Appendix II of Ford's petition details the steps to access the online owner's manual through ford.com/support, with similar instructions for the lincoln.com/support website. Ford further explains that customers can use the "Ford Pass" or "Lincoln Way" mobile applications, available free of charge, to view their vehicle's owner's manual. These mobile applications require users to download the application, register their vehicle, and have internet or cellular access on their mobile device.

Appendix III of Ford's petition specifies how a user can access the owner's manual through the "Ford Pass" mobile application, with similar steps for the "Lincoln Way" mobile application.

Ford reports that it searched its internal records and Vehicle Owner Questionnaires (VOQs) and found no evidence of customers experiencing confusion or lacking information regarding TPMS indicators or the

maintenance and inspection of seatbelt components. Ford found no other related complaints, accidents or injuries associated with the subject noncompliances. While Ford acknowledges that this fact is not dispositive, Ford considers it illustrative of the field performance.

Ford concludes by stating its belief that the subject noncompliances are inconsequential as they relate to motor vehicle safety and its petition to be exempted from providing notification of the noncompliances, as required by 49 U.S.C. 30118, and a remedy for the noncompliances, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that Ford no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicles distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Ford notified them that the subject noncompliances existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke, III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025–21530 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2024–0065; Notice 1]

Tesla, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Tesla, Inc. (Tesla) has determined that certain model year (MY) 2017–2023 Tesla Model 3 and MY 2020–2023 Model Y motor vehicles do

a subsequent OTA update restored the DOM for 26,368 of these vehicles. To address the missing DOM in the remaining 589 vehicles, a field service action was approved on June 2, 2023, and affected customers were mailed the full owner's manual and provided with instructions to restore the DOM either via another OTA or by visiting a dealership.

² Ford cites NHTSA's letter to The Honorable Bob Goodlatte, May 18, 2009, available at <https://www.nhtsa.gov/interpretations/09-002735-cong-goodlatte-2>.

³ Agency Information Collection Activities; Notice and Request for Comments; Consolidated Vehicles' Owner's Manual Requirements for Motor Vehicles and Motor Vehicle Equipment; 87 FR 9,790, February 22, 2022.

⁴ See Maserati North America, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance; 85 FR 45466 (July 28, 2020).

⁵ Ford cites NHTSA's letter to The Honorable Bob Goodlatte, May 18, 2009, available at <https://www.nhtsa.gov/interpretations/09-002735-cong-goodlatte-2>.

not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective Devices, and Associated Equipment*. Tesla filed a noncompliance report dated July 24, 2024, and subsequently petitioned NHTSA (the "Agency") on August 16, 2024, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces receipt of Tesla's petition.

DATES: Send comments on or before December 29, 2025.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and may be submitted by any of the following methods:

- **Mail:** Send comments by mail addressed to the 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 comments by hand to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.

- **Electronically:** Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Follow the online instructions for submitting comments.

- Comments may also be faxed to (202) 493-2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at <https://www.regulations.gov> by following the online instructions for accessing the dockets. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477-78).

FOR FURTHER INFORMATION CONTACT:

Kelley Adams-Campos, Safety Compliance Engineer, NHTSA, Office of Vehicle Safety Compliance, (202) 366-7479.

SUPPLEMENTARY INFORMATION:

I. Overview: Tesla determined that certain MY 2017-2023 Model 3 and MY 2020-2023 Model Y motor vehicles do not fully comply with paragraphs S7.3.13.1 and S7.1.2.13 of FMVSS No. 108, *Lamps, Reflective Devices, and Associated Equipment*. (49 CFR 571.108).

Tesla filed a noncompliance report dated July 24, 2024, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. Tesla petitioned NHTSA on August 16, 2024, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance*.

This notice of receipt of Tesla's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or another exercise of judgment concerning the merits of the petition.

II. Vehicles Involved: Approximately 6,025 MY 2017-2023 Model 3 and MY 2020-2023 Model Y, manufactured between November 9, 2017, and July 31, 2023, were reported by the manufacturer.

III. Rule Requirements: Paragraphs S7.3.13.1 and S7.1.2.13 of FMVSS No. 108 include the requirements relevant to this petition. Paragraphs S7.3.13.1 and S7.1.2.13 of FMVSS No. 108 require that each stop lamp be designed to conform to the photometry requirements of Table IX and Table VII, respectively. Table IX

and Table VII provide the minimum and maximum allowed stop lamp and rear turn signal lamp photometric intensity values for the number of lamp compartments or individual lamps, the type of vehicle it is installed on, and the lamp color. Table IX and VII each limit the stop and rear turn signal photometric intensity to 300 cd, 360 cd and 420 cd, for one, two and three lighted sections respectively.¹

IV. Noncompliance: Tesla explains that the subject vehicles may have been equipped with stop and rear turn signal lamps, as part of the left-hand rear combination lamp, that have a photometric intensity of 321.47 cd (candela), exceeding the maximum photometric intensity of 300 cd allowed by FMVSS No. 108 S7.3.13 and S7.1.2.13.

V. Summary of Tesla's Petition: The following views and arguments presented in this section, "V. Summary of Tesla's Petition," are the views and arguments provided by Tesla. They have not been evaluated by the Agency and do not reflect the views of the Agency. Tesla describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

Tesla was notified by Transport Canada on January 6, 2024, of a noncompliance with Canadian Motor Vehicle Safety Standard (CMVSS) No. 108 in the left-hand rear combination lamp of a 2019 Tesla Model 3. A Transport Canada contracted test laboratory tested the lamp and found that the stop lamp and turn signal lamp, part of the rear combination lamp, exceeded the photometric limits of CMVSS No. 108. After independently testing other left-hand rear combination lamps, Tesla concluded that the test sample is the only left-hand rear combination lamp that Transport Canada's contracted test laboratory, Tesla, or Tesla's supplier has tested that exceeded the photometric requirements of CMVSS/FMVSS No. 108. Tesla then made a voluntary recall determination on July 17, 2024.

Tesla argues that the noncompliance is inconsequential to motor vehicle safety because the difference between a lamp with compliant photometric intensity and the subject lamps' noncompliant photometric intensity is indistinguishable. For the affected stop and rear turn signal lamps, Tesla states that FMVSS No. 108 requires a photometric intensity of no more than

¹ Footnote (3) or Table IX and footnote (4) of Table VII state "the maximum photometric intensity must not occur over any area larger than that generated by a 0.5° radius within a solid angle defined by the test point range."

300 cd, but the subject lamps' output measured 321.47 cd at test point HV, or about seven percent higher than the maximum allowed. Tesla mentions two reports it says NHTSA has referred to in similar cases, *Driver Perception of Just-Noticeable Differences (of Automotive Signal Lamps)* (1994) and *Just Noticeable Differences for Low-Beam Headlamp Intensities* (1997), both of which Tesla says concluded that most drivers cannot distinguish differences of twenty-five percent or less in automotive lamp intensities. Because the photometric intensity of the subject lamps exceeds the requirement by seven percent, Tesla contends that, based on the findings of the two studies mentioned above, NHTSA should find that the difference between a compliant and noncompliant combination lamp is imperceptible and inconsequential to motor vehicle safety.

Tesla states that there are no complaints or reported accidents or injuries that may have been caused by this noncompliance. While Tesla acknowledges that a lack of complaints or reported accidents is not dispositive in the consideration of a petition for inconsequential noncompliance, Tesla states that this fact illustrates that field performance has not been otherwise affected by the noncompliance.

Tesla provides, in Section III of its petition, precedents that NHTSA has set by granting the following petitions for inconsequential noncompliance:

- A 1987 petition by Chrysler Corp. (52 FR 17499) for backup lamps that fell below the minimum required luminosity. Quoting the NHTSA decision—"... a deficiency of 20 [percent] in this area, spread over a population of only 800 cars, is statistically unlikely to produce even one injury over the lifetime of all the cars."

- A 1990 petition by Hella, Inc., (55 FR 37601) for taillamps with a luminosity at most 20 percent greater than the maximum luminosity allowed by regulation. Quoting NHTSA's decision—"The agency has also considered information indicating that a reduction of approximately 25 percent in luminous intensity is required before the human eye can detect the difference between two lamps."

- A 1991 petition by Subaru of America (56 FR 59971) for side reflex reflectors measured 20 percent below the minimum required luminous intensity. Quoting the decision by NHTSA—"a reduction of approximately 25 percent in luminous intensity is required before the human eye can detect the difference between two lamps."

- A 2019 petition by Toyota Motor North America, Inc., (85 FR 39679) for rear reflectors that failed to meet the minimum photometry requirements by as much as 18 percent below the required minimum. Tesla states that NHTSA's decision cited the aforementioned Hella and Subaru petitions and quotes NHTSA as stating—"imperceptible difference in illumination makes this noncompliance inconsequential to motor vehicle safety."

- Tesla also stated, in Section III of its petition, that "[i]n 2020, NHTSA granted Nissan North America, Inc.'s petition . . . related to front side marker lamps that do not meet the minimum photometric intensity requirement . . . by 15 [percent]." Tesla cited "87 FR 21259" in footnote 16 of its petition in relation to this petition. NHTSA notes that the citation 87 FR 21259 was the April 11, 2022, decision notice denying Nissan's petition for its noncompliance to the minimum required vertical gradient for headlamps.

Tesla states that the noncompliance in this case is similar to previously granted petitions for inconsequential noncompliance and distinguishable from similar petitions that were denied. Tesla provides two examples of denied petitions and argues why the petition in question is different.

- North American Subaru, Inc. filed a petition for inconsequential noncompliance in 2022 (87 FR 48764) for side reflex reflectors that were measured to be almost thirty percent below the required minimum luminosity. NHTSA denied the petition, stating "... NHTSA recognizes that the photometry criteria evaluated for reflex reflectors measured in (cd/incident ft-c) or (mcd/lux) whereas tail lamps are measured in candela (cd) and therefore it is not proper to apply the logic of the tail lamp analysis to reflect reflectors, despite the prior grant." Tesla states that, unlike this Subaru example, the subject noncompliant rear combination lamp is measured in cd., the signaling function is activated only in transient state, *i.e.*, during brake application and/or indication of driver intent to change vehicle course and that the noncompliant lamp is well within the twenty-five percent threshold established in the DOT and UMTRI studies and is therefore imperceptible to most drivers.

- Mercedes-Benz USA LLC, filed a petition for inconsequential noncompliance in 2016 (81 FR 21660) for headlamps that exceeded the maximum allowed photometric intensity by as much as forty percent.

Tesla states that the NHTSA decision to deny the petition was based on the headlamps being above the twenty-five percent threshold established in the DOT and UMTRI studies. The subject Tesla rear combination lamps measure only seven percent above the maximum allowed photometric intensity, rather than the forty percent in the denied Mercedes petition.

Tesla concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that Tesla no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicles distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Tesla notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,
Director, Office of Vehicle Safety Compliance.

[FR Doc. 2025-21523 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2025-0078]

Pipeline Safety: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44

United States Code (U.S.C.) § 3501 *et seq.*), this notice announces that the information collection requests abstracted below are being forwarded to the Office of Management and Budget (OMB) for review and comment. A **Federal Register** notice with a 60-day comment period soliciting comments on the information collections was published on July 15, 2025.

DATES: Interested persons are invited to submit comments on or before December 29, 2025.

ADDRESSES: The public is invited to submit comments regarding these information collection requests, including suggestions for reducing the burden, to Office of Management and Budget (OMB), Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW, Washington, DC 20503. Comments can also be submitted electronically at www.reginfo.gov/public/do/PRAMain.

FOR FURTHER INFORMATION CONTACT: Angela Hill by email at angela.hill@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Title 5, Code of Federal Regulations (CFR) § 1320.8(d), requires the Pipeline and Hazardous Materials Safety Administration (PHMSA) to provide interested members of the public and affected agencies the opportunity to comment on information collection and recordkeeping requests before they are submitted to OMB for approval. In accordance with this regulation, on July 15, 2025, PHMSA published a **Federal Register** notice (90 FR 31748) with a 60-day comment period soliciting comments on its intent to request OMB's renewed approval of the information collection requests that are due to expire in 2026.

During the 60-day comment period, PHMSA received comment from an anonymous commenter and a joint comment from the American Gas Association and the American Public Gas Association (AGA Joint Comment) pertaining to the proposed renewal of certain information collections. The AGA Joint Comment addressed: 1. New Customer Notifications for Excess Flow Valves; 2. Notification Requirements for Gas Transmission Pipelines; and 3. Amendments to Annual Report for Gas Distribution Operators. The comment expressed concerns that these information collection activities are unnecessary and do not contribute meaningfully to pipeline safety. The AGA Joint Comment also proposed regulatory changes to eliminate the notification requirements which would

need to be addressed through the formal rulemaking process. PHMSA has previously received input on notification requirements through rulemaking and RFIs,¹ and such feedback will be considered during those proceedings.

II. Summary of Impacted Collections

Section 1320.8(d), Title 5, Code of Federal Regulations, requires PHMSA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. PHMSA will request a three-year term of approval for each of the following information collection activities.

The following information is provided for each information collection: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping burden; and (8) Frequency of collection.

PHMSA requests comments on the following:

1. *Title:* Excess Flow Valves—New Customer Notifications.

OMB Control Number: 2137–0631.

Current Expiration Date: 01/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: This information collection covers the reporting and recordkeeping requirements for gas pipeline operators associated with customer notifications pertaining to the installation of excess flow valves. Gas pipeline operators must notify customers of their right to request the installation of excess flow valves and keep records of those notifications. This information collection request includes examples of language that can be used to notify natural gas customers of their right to request the installation of an excess flow valve. Use of the language is voluntary but would comply with Federal regulatory requirements.

Affected Public: Operators of natural gas and hazardous liquid pipeline systems and operators of liquefied natural gas facilities.

¹ See AGA and APGA (the Associations), Comments on Request for Information (RFI), Ensuring Lawful Regulation; Reducing Regulation and Controlling Regulatory Costs, FR 2025–05557 (May 5, 2025); Interstate Natural Gas Association of America, Comments on Request for Information, Ensuring Lawful Regulation; Reducing Regulation and Controlling Regulatory Costs, FR 2025–05557 (May 5, 2025); AGA, API, AFPM, APGA, GPA Midstream, INGAA, and NGA (the Associations), Comments on Pipeline Safety: Gas Pipeline Leak Detection and Repair, FR 2023–13900 (Aug. 16, 2023).

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 4,448.

Estimated annual burden hours: 4,448.

Frequency of collection: On occasion.

2. *Title:* Natural Gas Distribution Infrastructure Safety and Modernization Grant Program.

OMB Control Number: 2137–0641.

Current Expiration Date: 01/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: This information collection request covers the solicitation of applicant data from municipality- and community-owned utilities that are interested in applying to receive funds from the Natural Gas Distribution Infrastructure Safety and Modernization (NGDISM) Grant Program. Solicitation for grants under the NGDISM Grant Program is voluntary. To be eligible, however, municipality- and community-owned utilities must meet all the requirements set forth in the law. Therefore, PHMSA must collect certain information from applicants to determine eligibility and evaluate applications. PHMSA must also verify the accuracy of grant requests from approved applicants, in accordance with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and other laws and regulations governing Federal financial assistance programs, including (but not limited to) the Anti-Deficiency Act, the Federal Funding Accountability and Transparency Act (FFATA), the Payment Integrity Information Act of 2019, and 2 CFR part 200, among others. This information collection request also covers the submission of post-award data and environmental assessments of awarded projects.

Affected Public: Municipality- and Community-owned Utilities.

Annual Burden:

Estimated number of responses: 1,540.

Estimated annual burden hours: 39,840.

Frequency of collection: On occasion.

3. *Title:* Reporting Safety-Related Conditions on Gas, Hazardous Liquid, and Carbon Dioxide Pipelines and Liquefied Natural Gas Facilities.

OMB Control Number: 2137–0578.

Current Expiration Date: 03/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: This mandatory information collection request covers the collection of data on safety-related conditions occurring on a pipeline. 49 U.S.C. 60102

requires each operator of a pipeline facility (except master meter operators) to submit to DOT a written report on any safety-related condition that causes or has caused a significant change or restriction in the operation of a pipeline facility or a condition that is hazardous to life, property, or the environment.

Affected Public: Operators of natural gas pipeline systems, hazardous liquid pipeline systems, and liquefied natural gas facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 174.

Estimated annual burden hours: 1,044.

Frequency of Collection: On occasion.

4. Title: National Pipeline Mapping Program.

OMB Control Number: 2137–0596.

Current Expiration Date: 03/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: The Pipeline Safety Improvement Act of 2002 (Pub. L. 107–355), 49 U.S.C. 60132, “National Pipeline Mapping System,” requires operators of a pipeline facility (except distribution lines and gathering lines) to provide information to the Pipeline and Hazardous Safety Administration. Each operator is required to submit geospatial data appropriate for use in the National Pipeline Mapping System or data in a format that can be readily converted to geospatial data, the name and address of the person with primary operational control (to be known as its operator), and a means for a member of the public to contact the operator for additional information about the pipeline facilities it operates. Operators will submit the requested data elements once and make annual updates to the data if necessary. These data elements strengthen the effectiveness of PHMSA’s risk rankings and evaluations, which are used as a factor in determining pipeline inspection priority and frequency; allow for more effective assistance to emergency responders by providing them with a more reliable, complete data set of pipelines and facilities; and provide better support to PHMSA’s inspectors by providing more accurate pipeline locations and additional pipeline-related geospatial data that can be linked to tabular data in PHMSA’s inspection database.

Affected Public: Operators of natural gas and hazardous liquid pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses:

1,346.

Estimated annual burden hours:

162,208.

Frequency of Collection: On occasion.

5. Title: Hazardous Liquid Pipeline Operator Annual Reports.

OMB Control Number: 2137–0614.

Current Expiration Date: 03/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: The Federal pipeline safety regulations at 49 CFR 195.58 require operators of hazardous liquid pipelines to submit specific data on the safety of their pipelines annually. This mandatory information collection requires operators to submit data on the preceding year electronically by June 15th of each calendar year. This information is used by PHMSA to identify trends in hazardous liquid pipeline accidents and to identify operators who have poor safety records.

Affected Public: Operators of hazardous liquid pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 950.

Estimated annual burden hours: 18,050.

Frequency of collection: Annually.

6. Title: Hazardous Liquid Operator Notifications.

OMB Control Number: 2137–0630.

Current Expiration Date: 03/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: The pipeline safety regulations contained within 49 CFR part 195 require hazardous liquid operators to notify PHMSA in various instances. Section 195.414 requires hazardous liquid operators who are unable to inspect their pipeline facilities within 72 hours of an extreme weather event to notify the appropriate PHMSA Region Director as soon as practicable. Section 195.452 requires operators of pipelines that cannot accommodate an in-line inspection tool to file a petition in compliance with 49 CFR 190.9. These mandatory notifications help PHMSA to stay abreast of issues related to the health and safety of the Nation’s pipeline infrastructure.

Affected Public: Operators of hazardous liquid pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 110.

Estimated annual burden hours: 125.

Frequency of Collection: On occasion.

7. Title: Notification Requirements for Gas Transmission Pipelines.

OMB Control Number: 2137–0636.

Current Expiration Date: 03/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: A person owning or operating a natural gas pipeline facility is required to provide information to the Secretary of Transportation at the Secretary’s request according to 49 U.S.C. 60117. The pipeline safety regulations contained within 49 CFR part 192 require operators to make various notifications upon the occurrence of certain events. The provisions covered under this information collection request involve notification requirements for gas transmission pipeline operators who utilize alternative or expanded technologies and analyses when conducting tests and inspections. These notification requirements are necessary to ensure safe operation of transmission pipelines, ascertain compliance with gas pipeline safety regulations, and to provide a background for incident investigations. These mandatory notifications help PHMSA to stay abreast of issues related to the health and safety of the Nation’s pipeline infrastructure.

Affected Public: Operators of gas transmission pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 722.

Estimated annual burden hours: 1,070.

Frequency of Collection: On occasion.

8. Title: Transportation of Hazardous Liquids by Pipeline: Record keeping and Accident Reporting.

OMB Control Number: 2137–0047.

Current Expiration Date: 04/30/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: To ensure adequate public protection from exposure to potential hazardous liquid pipeline failures, PHMSA collects information on reportable hazardous liquid pipeline accidents. This mandatory information collection covers hazardous liquid pipeline accident report requirements in 49 CFR 195.50 and general record keeping burden associated with complying with Federal hazardous liquid pipeline safety regulations in Part 195. The definition of an “accident” and the reporting criteria for submitting a Hazardous Liquid Accident Report (form PHMSA F7000–1) is detailed in 49 CFR 195.54. Section 195.54 requires hazardous liquid operators to file an accident report, as soon as practicable, but not later than 30 days after discovery of the accident, on DOT Form 7000–1, whenever there is a reportable accident.

Affected Public: Operators hazardous liquid pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 1,646.

Estimated annual burden hours: 53,777.

Frequency of Collection: On occasion.
9. *Title:* Record keeping Requirements for Gas Pipeline Operators.

OMB Control Number: 2137–0049.

Current Expiration Date: 04/30/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: A person owning or operating a natural gas pipeline facility is required to maintain records, make reports, and provide information to the Secretary of Transportation at the Secretary's request. This mandatory information collection request would require owners and/or operators of gas pipeline systems to make and maintain records in accordance with the requirements prescribed in 49 CFR part 192 and to provide information to the Secretary of Transportation at the Secretary's request. Certain records are maintained for a specific length of time while others are required to be maintained for the life of the pipeline. PHMSA uses these records to verify compliance with Federal pipeline safety regulations and to inform the Agency of possible safety risks.

Affected Public: Operators natural, and other, gas pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 3,861,842.

Estimated annual burden hours: 1,677,030.

Frequency of Collection: On occasion.
10. *Title:* Annual Report for Gas Distribution Operators.

OMB Control Number: 2137–0629.

Current Expiration Date: 06/30/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: This information collection request requires operators of gas distribution pipeline systems to submit annual report data to PHMSA in accordance with 49 CFR part 191 using PHMSA F 7100.1–1. The form is to be submitted once for each calendar year. The annual report form collects data about the pipe material, size, and age. The form also collects data on leaks from these systems as well as excavation damages. PHMSA uses the information to track the extent of gas distribution systems and normalize incident and leak rates.

Affected Public: Operators gas distribution pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 1,446.

Estimated annual burden hours: 28,920.

Frequency of Collection: Annually.

11. *Title:* Incident Reports for Natural Gas Pipeline Operators.

OMB Control Number: 2137–0635.

Current Expiration Date: 06/30/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: Operators of natural gas pipelines and liquefied natural gas (LNG) facilities are required to report incidents, on occasion, to PHMSA per the requirements in 49 CFR part 191. This mandatory information collection covers the collection of incident report data from natural gas pipeline operators. This information is an essential part of PHMSA's overall effort to minimize natural gas transmission, gathering, and distribution pipeline failures.

Affected Public: Operators gas pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 840.

Estimated annual burden hours: 2,927.

Frequency of Collection: On occasion.
12. *Title:* Annual and Incident Reports for Gas Pipeline Operators.

OMB Control Number: 2137–0522.

Current Expiration Date: 08/31/2026.

Type of Request: Renewal, without change, of a currently approved information collection.

Abstract: This mandatory information collection covers the collection of data from operators of natural gas pipelines, underground natural gas storage facilities, and LNG facilities for annual reports. Section 191.17 requires operators of the affected systems to submit an annual report by March 15, for the preceding calendar year.

Affected Public: Operators gas pipeline systems.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 2,445.

Estimated annual burden hours: 104,596.

Frequency of Collection: On occasion.
Comments are invited on:

(a) The need for the renewal of these information collections for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) The accuracy of the Agency's estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used;

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

(d) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended, and 49 CFR 1.48.

Issued in Washington, DC under authority delegated in 49 CFR 1.97.

John A. Gale,

Director, Standards and Rulemaking Division.

[FR Doc. 2025–21491 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2025–1161]

**Agency Information Collection:
Activity for OMB Review: Agency
Request for Reinstatement of a
Previously Approved Information
Collection: 2105–0009, Advisory
Committee Candidate Biographical
Information Request Form**

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (Department or DOT).

ACTION: Notice; request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Department invites the general public, industry, and other government parties to comment on the information collection request (ICR) OMB No. 2105–0009, “Committee Candidate Biographical Information Request Form.” The information collection request previously approved by the Office of Management and Budget (OMB) expired on May 3, 2022. The collection is needed to facilitate background investigations of individuals seeking appointment to a Departmental committee.

DATES: Written comments should be submitted by December 29, 2025.

FOR FURTHER INFORMATION CONTACT: Ashleigh Schofield, Supervisory Writer-Editor, Executive Secretariat, U.S. Department of Transportation, (771) 241–9281, Ashleigh.Schofield@dot.gov. Refer to “OMB Control No. 2105–0009.”

ADDRESSES: All comments should refer to the docket number above and be submitted by one of the following methods:

• *Federal Rulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments.

• *Mail*: Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery*: 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

Instructions: All comments must include the agency name and Docket DOT–OST–2025–1161. Note that all comments received will be posted without change to <https://www.regulations.gov>, including personal information provided. You should know that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an associate, business, labor union, etc.).

SUPPLEMENTARY INFORMATION:

Title: Committee Candidate Biographical Information Request.

OMB Control No.: 2105–0009.

Type of Review: Reinstatement without change of previously approved information collection.

Form No.: DOT F1120.1.

Respondents: Individuals who have contacted DOT to indicate interest in appointment to a committee and individuals who have been recommended for membership on a committee. Only one collection is expected per individual.

Number of Respondents: 250 annually.

Frequency: One time.

Estimated Time per Response: 15 minutes.

Total Annual Burden: 62.5 hours.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will be have practical utility; (b) the accuracy of the Department's estimate of burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information collection; and (d) ways to minimize the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology without reducing the quality of the information collected. All comments will become a matter of public record.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued in Washington, DC

Ashleigh Schofield,

Supervisory Writer-Editor, Executive Secretariat.

[FR Doc. 2025–21572 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2025–1524]

Privacy Act of 1974; System of Records

AGENCY: Office of the Departmental Chief Information Officer, Office of the Secretary of Transportation, DOT.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the United States Department of Transportation (DOT) proposes a new system of records titled, “Department of Transportation, Federal Aviation Administration DOT/FAA 859, Passport and Visa Tracking Records.” This system of records allows the FAA to collect, use, and maintain information needed to track progress on passport and visa applications, and expiration dates on official passports for employees and members of the public, such as an employee's dependent(s).

DATES: Submit comments on or before December 29, 2025. The Department may publish an amended Systems of Records Notice (hereafter “Notice”) in light of any comments received. This new system will be effective immediately. The routine uses will be effective December 29, 2025.

ADDRESSES: You may submit comments identified by docket number DOT–OST–2025–1524 by any of the following methods:

• *Federal e-Rulemaking Portal*: <https://www.regulations.gov>. Follow the instructions for submitting comments.

• *Mail*: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery or Courier*: West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.

• *Fax*: (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2025–1524. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: For questions, please contact: Karyn Gorman, Departmental Chief Privacy Officer, Privacy Office, Department of Transportation, Washington, DC 20590; privacy@dot.gov; or 202–366–3140.

SUPPLEMENTARY INFORMATION:

Background

The Office of Policy, International Affairs and Environment, at the FAA receives passport and visa applications from FAA employees who travel or work overseas on official government business. Employees who travel overseas on official government business are typically assigned official or red cover passports, whereas those employees who work overseas and are accompanied by their dependent(s) are assigned diplomatic or black cover passports. Data from the passport and visa applications is entered into the FAA information system to track the progress of these applications and the expiration dates of official and diplomatic passports. The Office of Policy, International Affairs and Environment, submits passport applications to the Department of State and visa applications to the respective embassies in Washington, DC for processing. The FAA does not retain any application related documentation submitted to them by employees and only tracks the progress of these applications.

In order to track passport and visa applications, the FAA collects the names, dates of birth, passport and visa numbers, passport and visa issuance and expiration dates, issuing country for visas, country(ies) visited, email addresses, positions/titles, organizations, lines of business, dates of official travel and various dates throughout the passport and visa application process (for tracking purposes) from FAA employees and members of the public, such as employees' dependent(s). Information on an employee's minor dependents is obtained directly from the employee.

Privacy Act

The Privacy Act (5 U.S.C. 552a) governs how the Federal Government collects, maintains, and uses personally identifiable information (PII) in a System of Records. A "System of Records" is a group of any records under the control of a federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a System of Records Notice (SORN) identifying and describing each System of Records the agency maintains, including the purposes for which the agency uses PII in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals to whom a Privacy Act record pertains can exercise their rights under the Privacy Act (e.g., to determine if the system contains information about them and to contest inaccurate information). In accordance with 5 U.S.C. 552a(r), DOT has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Department of Transportation (DOT)/ Federal Aviation Administration (FAA) 859 Passport and Visa Tracking Records.

SECURITY CLASSIFICATION:

Unclassified, Sensitive

SYSTEM LOCATION:

The primary hosting site is the Tier Point Olive Data Center, 1111 Olive Street, St. Louis, MO 63101. The alternate hosting site is the Tier Point Bellevue Data Center, 1001 North Fort Crook Road, Bellevue, NE 68005.

SYSTEM MANAGER(S):

Director, National Labor and Employee Relations (LER) Systems and Programs, AHL-400, Office of Labor and Employee Relations, Federal Aviation Administration (FAA), 800 Independence Avenue SW, Washington, DC 20591; Phone: 202-267-0931.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

22 U.S.C. 211a.

PURPOSE(S) OF THE SYSTEM:

To allow the FAA to track the passport and visa applications as well as expiration dates of official and diplomatic passports of employees and members of the public, such as employee's dependent(s).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

FAA employees and members of the public, such as employees' dependent(s).

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system includes names, dates of birth, passport and visa numbers, passport and visa issuance and expiration dates, issuing country for visas, country(ies) visited, email addresses, positions/titles, organizations, lines of business, dates of official travel and various dates for the passport and visa application process (for tracking purposes).

RECORD SOURCE CATEGORIES:

Records are obtained from current FAA employees and members of the public, such as employee's adult dependent(s). Information on an employee's minor dependents is obtained directly from the employee.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to other 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 DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. In the event that a system of records maintained by DOT to carry out its functions 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, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

2. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a DOT decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

3. A record from this system of records may be disclosed, as a routine use, to a Federal agency, in response to

its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4a. Routine Use for Disclosure for Use in Litigation. It shall be a routine use of the records in this system of records to disclose them to the Department of Justice, or other Federal agencies conducting litigation when (a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof in their official capacity, or (c) Any employee of DOT or any agency thereof, in their individual capacity, where the Department of Justice has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that litigation likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other Federal agency conducting the litigation is deemed by DOT to be relevant and necessary in the litigation, provided, however, that in each case, DOT determines that disclosure of the records in the litigation is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

4b. Routine Use for Agency Disclosure in Other Proceedings. It shall be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which DOT or any agency thereof appears when (a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof in their official capacity, or (c) Any employee of DOT or any agency thereof in their individual capacity where DOT has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that the proceeding is likely to affect the United States, is a party to the proceeding, or has an interest in such proceeding, and DOT determines that use of such records is relevant and necessary in the proceeding, provided, however, that in each case, DOT determines that disclosure of the records in the proceeding is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

5. The information contained in this system of records will be disclosed to the Office of Management and Budget, OMB in connection with the review of

private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

6. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual. In such cases, however, the congressional office does not have greater rights to records than the individual. Thus, the disclosure may be withheld from delivery to the individual where the file contains investigative or actual information or other materials which are being used, or are expected to be used, to support prosecution or fines against the individual for violations of a statute, or of regulations of the Department based on statutory authority. No such limitations apply to records requested for Congressional oversight or legislative purposes; release is authorized under 49 CFR 10.35(9).

7. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration (NARA) in records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

8. Routine Use for disclosure to the Coast Guard and to the Transportation Security Administration. A record from this system of records may be disclosed as a routine use to the Coast Guard and to the Transportation Security Administration if information from this system was shared with either agency when that agency was a component of the Department of Transportation before its transfer to the Department of Homeland Security and such disclosure is necessary to accomplish a DOT, TSA or Coast Guard function related to this system of records.

9. DOT may make available to another agency or instrumentality of any government jurisdiction, including State and local governments, listings of names from any system of records in DOT for use in law enforcement activities, either civil or criminal, or to expose fraudulent claims, regardless of the stated purpose for the collection of the information in the system of records. These enforcement activities are generally referred to as matching programs because two lists of names are checked for match using automated assistance. This routine use is advisory in nature and does not offer unrestricted access to systems of records for such law enforcement and related antifraud activities. Each request will be considered on the basis of its purpose, merits, cost effectiveness and

alternatives using Instructions on reporting computer matching programs to the Office of Management and Budget, OMB, Congress, and the public, published by the Director, OMB, dated September 20, 1989.

10. It shall be a routine use of the information in any DOT system of records to provide to the Attorney General of the United States, or his/her designee, information indicating that a person meets any of the disqualifications for receipt, possession, shipment, or transport of a firearm under the Brady Handgun Violence Prevention Act. In case of a dispute concerning the validity of the information provided by DOT to the Attorney General, or his/her designee, it shall be a routine use of the information in any DOT system of records to make any disclosures of such information to the National Background Information Check System, established by the Brady Handgun Violence Prevention Act, as may be necessary to resolve such dispute.

11a. DOT may disclose records from this system, as a routine use, to appropriate agencies, entities, and persons when: (1) DOT suspects or has confirmed that there has been a breach of the system of records; (2) DOT has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOT (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 DOT's efforts to respond to the suspected or confirmed breach or to prevent, minimize or remedy such harm.

11b. To another Federal agency or Federal entity, when DOT 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.

12. DOT may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (a) resolving disputes between FOIA requesters and Federal agencies and (b) reviewing agencies policies, procedures and compliance in order to recommend

policy changes to Congress and the President.

13. DOT may disclose records from this system, as a routine use, to contractors and their agents, experts, consultants, and other performing or working on a contract, service, cooperative agreement, or other assignment for DOT, when necessary to accomplish an agency function related to this system of records.

14. DOT may disclose records from this system, as a routine use, to an agency, organization or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under Section (b)(1) of the Privacy Act.

15. DOT may disclose from this system, as a routine use, records consisting of, or relating to, terrorism information (6 U.S.C. 485(a)(5)), homeland security information (6 U.S.C. 482(f)(1)), or Law enforcement information (Guideline 2 Report attached to White House Memorandum, "Information Sharing Environment," November 22, 2006) to a Federal, State, local, Tribal, Territorial, foreign government and/or multinational agency, either in response to its request or upon the initiative of the component for purposes of sharing such information as is necessary and relevant for the agencies to detect, prevent, disrupt, preempt, and mitigate the effects of terrorist activities against the territory, people and interests of the United States of America, as contemplated by the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108-458) and Executive Order 13388 (October 25, 2005).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in an electronic database.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are primarily retrieved by personal identifiers, such as name, passport and visa numbers.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Passport and visa application records will be maintained in accordance with National Archives and Records Administration General Records Schedule (GRS) 2.2, item 90, Official Passports Records. Records are destroyed when 3 years old or upon employee separation or transfer, whichever is sooner, but longer

retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DOT and FAA automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of whether this system of records contains information about them may contact the System Manager at the address provided in the section "System Manager". When seeking records about yourself from this system of records or any other Departmental system of records your request must conform to the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

CONTESTING RECORD PROCEDURES:

See "Record Access Procedures" above.

NOTIFICATION PROCEDURES:

See "Record Access Procedures" above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Issued in Washington, DC.

Karyn Gorman,

Departmental Chief Privacy Officer.

[FR Doc. 2025-21358 Filed 11-26-25; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket ID Number: DOT-OST-2010-0054]

Notice of Submission of Proposed Information Collection to OMB; Agency Request for Renewal of Previously Approved Collections: Nondiscrimination on the Basis of Disability in Air Travel: Reporting Requirements for Disability-Related Complaints

AGENCY: Office of the Secretary (OST), Department of Transportation (Department or DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the *Paperwork Reduction Act of 1995* (44 U.S.C. Chapter 35, as amended), this notice announces DOT's intention to renew Office of Management and Budget (OMB) Control Number 2105-0551, "Reporting Requirements for Disability-Related Complaints." The information collection is related to a requirement in the Code of Federal Regulations (CFR) for carriers to report annually to the Department the number of disability-related complaints they receive.

DATES: Interested persons are invited to submit comments regarding this proposal. Written comments should be submitted by January 27, 2026.

ADDRESSES: You may submit comments identified by Docket No. DOT-OST-2010-0054 through one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590.
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

Instructions: Enter the agency name and docket number at the beginning of your comment. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

Privacy Act: Anyone may search the electronic form of all comments received in any of DOT's dockets by the name and individual submitting the comment (or signing the comment, if submitted on behalf of an association,

business, labor union, etc.). You may review the System of Records Notice covering the Federal Docket Management System at 73 FR 3116-17.

FOR FURTHER INFORMATION CONTACT: John Wood, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Telephone Number (202) 366-9342 (voice), C70notice@dot.gov (email).

SUPPLEMENTARY INFORMATION: *OMB Control Number:* 2105-0551.

Title: Reporting Requirements for Disability-Related Complaints.

Type of Request: Renewal of information collections.

Background: The Department's regulation 14 CFR 382.157 requires U.S. and foreign air carriers operating to, from, and within the United States that conduct passenger-carrying service with at least one aircraft with a designed seating capacity of more than 60 passengers (large aircraft) to record disability-related complaints that they receive. For the purposes of the requirement, a disability-related complaint means a specific written expression of dissatisfaction received from, or submitted on behalf, of an individual with a disability concerning a difficulty associated with the person's disability, which the person experienced when using or attempting to use an air carrier's or foreign carrier's services. The carriers must also categorize these complaints according to the type of disability and nature of complaint, prepare a summary report annually of the complaints received during the preceding calendar year, submit the report to the Department's Office of Aviation Consumer Protection, and retain copies of correspondence and records of action taken on the reported complaints for three years. Carriers are required to submit their annual report to the Department by the last Monday in January of each year for complaints received during the prior calendar year.

Carriers report annually the information described in Appendix A to 14 CFR 382 "Report of Disability-Related Complaint Data" (Reporting Form). DOT regulations provide that carriers must submit their reports using the World Wide Web unless approved by DOT to use another method. See 14 CFR 382.157. The Department intends to use its newly modernized Aviation Complaint, Enforcement, and Reporting System (ACERS), a web-based portal, to accept annual disability reports from carriers beginning with annual reports for calendar year 2025 operations. These reports will be due January 26, 2026.

To file a report using ACERS, an authorized air carrier representative will use the organization's ACERS account information to log into ACERS and access the web-based version of the Reporting Form to enter the information, including contact information, complaint data, and certification information. Then, the representative will click "Submit" which will electronically transmit the report to the Department.

Among other things, ACERS was developed to offer air carriers and other industry users improved disability reporting efficiencies and capabilities. More specifically, ACERS will enable a carrier receiving "0" disability-related complaints during a particular reporting year to, with one click, auto-populate each field of the report with a "0" instead of selecting each field separately and then entering a "0." In addition, ACERS allows carrier representatives to save their progress on partially completed reports, so that they may return to edit and complete their report without losing information entered previously.

Reporting carriers must be registered with the Department to receive a log-in for ACERS prior to filing a report using the system. Information collection activities, including burden estimates, for air travel industry representatives and other users to create and manage ACERS accounts and to use ACERS functionalities to submit reports, in general, are covered under a separate OMB Control Number (2105-0568) which is valid through August 31, 2027. OMB Control Number 2105-0551, which is addressed by this notice, covers burdens associated with preparing and submitting the annual disability report to the Department. OMB Control Number 2105-0551 is valid through January 31, 2026.

The Department relies on the disability-related complaint information collections primarily to comply with 49 U.S.C. 41705(c)(3), which requires the Secretary of Transportation to "regularly review all complaints received by carriers alleging discrimination on the basis of disability" and "report annually to Congress on the results of such review." The Department may also rely on this information to inform policy and in enforcement matters. The Department publishes the data collected from airlines each year, and the corresponding reports to Congress, on its website at: <https://www.transportation.gov/airconsumer/annual-report-disability-related-air-travel-complaints>.

The Paperwork Reduction Act of 1995 (PRA) and its implementing regulations,

5 CFR 1320, *et seq.*, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to monetary penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

For each information collection, the title, a description of the respondents, and an estimate of the annual recordkeeping and periodic reporting burden are set forth below.

(1) Requirement to record and categorize complaints received.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 170 (the total number of respondents that reported for Calendar Year (CY) 2023).¹

Frequency: 49,082 complaints per year total for all respondents, which represents the number of complaints received by all respondents combined during CY 2023 (0–9,717 complaints is the range of the lowest number of complaints and the highest number of complaints received by any respondent during CY 2023).

Estimated Burden on Respondents: .25 hours on each respondent to categorize and record each complaint.

Estimated Total Annual Burden: 12,270.5 hours for all respondents (time to record and categorize each complaint (.25 hours) multiplied by the total number of complaints received during CY 2023 (49,082)). On average, the estimated annual burden per respondent is a range of 0–2,429.25 hours per carrier.

(2) Requirement to prepare and submit annual report.

Carriers will generally submit their reports electronically through ACERS or another means approved by the Department.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

¹ As of the date of this notice, disability-related complaints data for CY 2023 are the most recent data available to the Department.

Number of Respondents: 170 (the total number of respondents that reported for CY 2023).

Frequency: 1 report to DOT per year for each respondent.

Estimated Burden on Respondents: 0.5 hours a year for each respondent to report to DOT.

Estimated Total Annual Burden: 85 hours for all respondents (time to report (0.5 hours) multiplied by 170, the total number of respondents).

(3) Requirement to retain correspondences and records of action taken on all disability-related complaints.

Respondents: U.S. air carriers and foreign air carriers operating to and from the United States that conduct passenger-carrying service with at least one large aircraft.

Number of Respondents: 170 (the total number of respondents that reported for CY2023).

Frequency: 49,082 complaints per year total for all respondents, which represents the number of complaints received by all respondents combined during CY 2023 (0–9,717 complaints is the range of the lowest number of complaints and the highest number of complaints received by any respondent during CY 2023).

Estimated Burden on Respondents: 0.083 (repeating) hours per complaint (the time it takes for a respondent to retain or save the correspondences and records of action taken on a single disability-related complaint).

Estimated Total Annual Burden: 4,090.17 hours (time it takes for a respondent to retain or save the correspondences and records of action taken on a single disability-related complaints (0.083 (repeating) hours) multiplied by the total number of complaints received during CY 2023 (49,082)).

Comments Invited

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (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. All comments will also become a matter of public record on the docket.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.26, 1.27, 1.48; DOT Order 1351.29.

Issued in Washington, DC.

Liv Vaughn Chapman, Jr.,

Deputy Assistant General Counsel.

[FR Doc. 2025–21364 Filed 11–26–25; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2025–0537]

Request for Information Regarding Community Banks' Engagement With Core Service Providers and Other Essential Third-Party Service Providers

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Request for information and comment.

SUMMARY: The OCC is issuing a request for information (RFI) on community bank engagement with their core service providers and other essential third-party service providers. The RFI seeks to better understand how challenges community banks face with such service providers affect these banks' abilities to remain competitive in a rapidly evolving marketplace, as well as what actions the OCC can take to address any of these challenges.

DATES: Comments must be received by January 27, 2026.

ADDRESSES: Commenters are encouraged to submit comments through the Federal eRulemaking Portal. Please use the title "Request for Information Regarding Community Banks' Engagement with Core Service Providers and Other Essential Third-Party Service Providers" to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal—Regulations.gov:*

Go to <https://regulations.gov/>. Enter Docket ID "OCC–2025–0537" in the Search Box and click "Search." Public comments can be submitted via the "Comment" box below the displayed document information or by clicking on the document title and then clicking the "Comment" box on the top-left side of the screen. For help with submitting effective comments, please click on "Commenter's Checklist." For assistance with the *Regulations.gov* site, please call 1–866–498–2945 (toll free) Monday–Friday, 9 a.m.–5 p.m. EST, or email regulationshelpdesk@gsa.gov.

- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office

of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

Instructions: You must include "OCC" as the agency name and Docket ID "OCC–2025–0537" in your comment. In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website without change, including any business or personal information provided such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this action by the following method:

- *Viewing Comments Electronically—Regulations.gov:*

Go to <https://regulations.gov/>. Enter Docket ID "OCC–2025–0537" in the Search Box and click "Search." Click on the "Dockets" tab and then the document's title. After clicking the document's title, click the "Browse All Comments" tab. Comments can be viewed and filtered by clicking on the "Sort By" drop-down on the right side of the screen or the "Refine Comments Results" options on the left side of the screen. Supporting materials can be viewed by clicking on the "Browse Documents" tab. Click on the "Sort By" drop-down on the right side of the screen or the "Refine Results" options on the left side of the screen checking the "Supporting & Related Material" checkbox. For assistance with the *Regulations.gov* site, please call 1–866–498–2945 (toll free) Monday–Friday, 9 a.m.–5 p.m. EST, or email regulationshelpdesk@gsa.gov.

The docket may be viewed after the close of the comment period in the same manner as during the comment period.

FOR FURTHER INFORMATION CONTACT:

Daniel Amodeo, Counsel and Graham Bannon, Counsel, Chief Counsel's Office, 202–649–5490. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION:

I. Introduction

Community banks¹ have an outsized impact on lending and are vital to the strength of the U.S. economy. The OCC has committed to prioritizing reforms targeted at reducing the supervisory and regulatory burden for community banks and exploring efforts to tailor our regulation and supervisory frameworks to better fit their business models and unique risks—better positioning these banks to support their communities and drive economic growth. Many community banks are dependent on third parties to operate effectively and competitively in an increasingly online marketplace. This includes those third parties that provide the comprehensive back-end applications and infrastructure that support the operation and essential functions of one or more of the bank's lines of business, including, for example, through the provision of transaction processing, account management, payments processing, customer relationship management, compliance and reporting, online banking, and other material functions (core service providers). It also includes those third parties who provide other essential functions supporting those core functions, including cloud processing, cloud storage, artificial intelligence, and compliance tools.

The OCC is aware that continued consolidation in the core service provider and other essential third-party service provider markets can result in reduced competitive pressure to provide innovative and effective solutions for community banks; reduced negotiating power for many community banks vis-à-vis their core service providers, resulting in potentially burdensome contractual provisions and bundled products that raise fees; and a sense that many community banks do not believe that their core service providers and other essential third-party service providers are partners committed to their long-term success. According to one survey, for example, the three largest core service providers served more than 70% of depository institutions in 2022, with the largest core service provider alone serving 42% of depository institutions.² At the same time, the OCC is aware that many of these same banks believe these potentially anti-competitive forces are

¹ The term "banks" as used in this RFI means national banks and Federal savings associations.

² See Julian Alcazar, et al., Federal Reserve Bank of Kansas City, Payments System Research Briefing, "Market Structure of Core Banking Services Providers" (Mar. 27, 2024), available at: <https://www.kansascityfed.org/documents/10072/PaymentsSystemResearchBriefing24AlcazarBairdCronenwehHayashilsaacson0327.pdf>.

preventing them from taking full advantage of the rapid pace of innovation in the financial technology marketplace, leaving them exposed to changing consumer expectations they may not be able to meet. Polling by community bank trade groups continues to show high levels of dissatisfaction with core service providers—one recent poll showed that, on a scale of 1 to 5, respondent depository institutions reported an overall satisfaction level of 3.19 and rated the effectiveness of their core service providers at 2.78, with certain of the largest core service providers and their products consistently receiving lower scores than many of their smaller peers.³ While financial technology firms, new core service provider entrants, and bank-developed core services have attempted to break into the market and address these concerns, the increasingly high capital costs associated with switching core service providers or other essential third-party service providers or developing technological solutions in-house prevent many community banks benefiting from these developments.

The OCC seeks public comment on community banks' engagement with their core service providers and other essential third-party service providers, especially as it relates to community banks' ability to remain competitive in a rapidly evolving marketplace. The OCC also welcomes comment on any aspect of other third-party service provider activities, relationships, or supervisory or regulatory burdens insofar as they relate to core service providers and other essential third-party service providers. This includes whether and to what extent any of the agency's supervisory guidance or regulatory requirements may exacerbate the concerns described in this RFI or otherwise impose undue burdens on community banks in managing their relationships with their core service providers and other essential third-party service providers.⁴ This RFI is designed to supplement the agency's understanding of the challenges community banks face in their relationships with these service providers and help the agency develop a roadmap for supervisory and

regulatory actions to consider these concerns.

II. Background

This RFI stems from commenters' concerns noted in response to the OCC's May 12, 2025, Request for Information Regarding Community Bank Digitalization.⁵ The OCC received 22 comments from community banks, industry groups, technology providers, and other interested parties. Although focused on the use of technology to change a business model, provide new revenue and value-producing opportunities, or automate business processes, the agency also received numerous and varied comments on community banks' relationships with their core service providers and other essential third-party service providers. Some of these commenters expressed concerns about predominant market reliance on the largest core service providers, resulting in reduced bargaining power and difficulty integrating new technology with legacy platforms for community banks.⁶

To better understand these comments and create a detailed record to support potential agency action, the OCC conducted informal outreach with various community banks. Broadly speaking, these community banks identified the following concerns with certain core service providers and other essential third-party service providers that they had either experienced or else were concerned could limit their bank's ability to remain competitive:

- insufficient investment in innovation to ensure services are keeping pace with market developments and perceived long development timelines for new services;
- use of dated programming languages leading to difficulties

⁵ 90 FR 20212 (May 12, 2025).

⁶ In addition to comments on core service providers and other third-party service providers, the OCC also received comments broadly along the lines of the following two themes:

- *Resource Constraints:* Commenters noted community banks' difficulties in attracting and retaining sufficient staff with the requisite skills to undertake modernizing digitalization projects, as well as budget limitations and concerns around managing existing technology debt.
- *Regulatory Clarity:* Commenters suggested various ways that the agency could improve regulatory clarity to reduce burden on community banks, including that the agency consider establishing sandboxes, pilot programs, or safe harbors related to digitalization activities; engage in public-private dialogues and knowledge exchanges; and issue no-action letters, reinstitute certain FAQs, revise existing guidance (in particular, the TPRM Guidance), or publish range-of-practice or lessons-learned documents expressing observations on leading and lagging practices.

The OCC continues to review these comments to identify and craft responsive actions to support community banks' digitalization efforts.

integrating the services of acquired companies into a comprehensive, unified package and posing interoperability with other third-party service providers;

- limitations on the use of unaffiliated third parties;
- limitations on, and fees related to, accessing and leveraging bank-owned data, including in a format that is comprehensive and compatible with modern operating systems;
- use of non-disclosure agreements that impede the free flow of information on core service providers' pricing, services, and contract terms;
- bundling of unnecessary supplemental services leading to increased fees (though some banks also acknowledged that lengthened terms may result in lower prices);
- costs and limitations surrounding service terminations and core conversions (though some banks noted that termination fees may be somewhat offset by buyouts from rival core service providers), together with increased contract term lengths; and
- overly lengthy and confusing billing practices requiring significant manhours to catch repeated billing errors.

Several community banks also noted positive relationships with certain specific core service providers. These community banks noted that such core service providers treat the arrangement as a long-term relationship, allow and encourage their customer banks to submit requests as to desired new services, provide application program interfaces (APIs) with limited restrictions that allow unaffiliated third-party service providers to seamlessly plug into the core service provider's platform, and maintain data in up-to-date formats.

Community banks that participated in these listening sessions almost unanimously voiced concerns about the ability of their core service providers to supply community banks, on a timely basis, with the products, services, and solutions they need to remain competitive in a rapidly evolving marketplace, particularly with regard to the growing stablecoin and crypto-asset markets and to changes to the banking industry that may accompany recent and ongoing developments in artificial intelligence.

The OCC also notes that the Financial Stability Oversight Council has also repeatedly noted similar concerns and has supported the Federal banking agencies and other agencies addressing the risks that core service providers and other essential third-party service providers pose to financial institutions

³ See American Bankers Association, "2024 ABA Core Platforms Survey: All Core Platform Providers Are Not the Same" (Feb. 2025), available at: <https://www.aba.com/-/media/documents/reference-and-guides/2024-core-platform-survey.pdf?rev=f282f2c8fa1048dc8ab157ff8d9855ac>.

⁴ Including, for example, the *Interagency Guidance on Third-Party Relationships: Risk Management*. See 88 FR 37920 (June 9, 2023) (TPRM Guidance).

that could spread and undermine financial stability.⁷

III. Questions

The OCC notes that it is vital for U.S. economic security that community banks be able to remain competitive in a rapidly evolving marketplace. As such, the OCC is seeking further information on any barriers community banks face in remaining competitive and any responsive actions that the agency could take. The agency also reminds core service providers and other essential third-party service providers that certain services they perform for a bank are subject to regulation and examination by the agency to the same extent as if such services were being performed by a client bank itself on its own premises.⁸

The OCC seeks input from community banks, industry groups, service providers, and other interested parties regarding the challenges and barriers in all aspects of community banks' relationships with their core service providers and other essential third-party service providers. These may include challenges and barriers related to:

- contract negotiations;
- the scope and burden of applicable fees;
- billing practices and concerns;
- oversight of core service providers and other third-party service providers;
- the ability to terminate relationships with core service providers in breach of contracts, including service-level agreements;
- any burdens limiting banks' ability to undertake core conversions that are

beyond those inherent in such a process;

- the extent to which interoperability between core service providers and other third-party service providers may facilitate or inhibit innovations necessary for community banks to remain competitive in a rapidly evolving marketplace;
- supervisory expectations and guidance, including the Third Party Risk Management (TPRM) Guidance, or regulatory requirements; and
- potential actions the OCC could take to address these concerns and other relevant topics.

In addition, we invite the relevant stakeholder to respond to the following specific questions:

Innovation

1. What challenges have community banks faced, or do they expect to face, in relation to their core service providers and other essential third-party service providers in implementing innovative solutions or accessing services necessary for community banks to remain competitive in a rapidly evolving marketplace? What are examples where a bank believes its service providers have been able or unable to provide innovative solutions and adaptations, and what lessons can be learned from such experiences?

2. What challenges have community banks faced, or do they expect to face, in relation to their core service providers and other essential third-party service providers in responding to the growing stablecoin and crypto-asset markets? How might the OCC address those concerns through regulatory and supervisory authority? How might the exercise of OCC regulatory or supervisory authority complicate challenges community banks face in this area?

3. What challenges have community banks faced, or do they expect to face, in relation to their core service providers and other essential third-party service providers in responding to developments in artificial intelligence? How might the OCC address those concerns through regulatory and supervisory authority? How might the exercise of OCC regulatory or supervisory authority complicate challenges community banks face in this area?

4. What challenges do community banks face in verifying the feasibility and effectiveness of innovative solutions offered or marketed by core service providers and other essential third-party service providers, or otherwise achieving visibility into such solutions? How do community banks

ensure that the innovative solutions offered by these service providers truly meet their operational and strategic needs?

5. What challenges do community banks face in ensuring the availability and quality of post-implementation support from core service providers and other essential third-party service providers?

6. What challenges do community banks face in assessing the scalability and flexibility of core service providers' and other essential third-party service providers' solutions to ensure they can grow with the bank's needs?

7. What challenges do community banks face when they decide to extract and leverage their data maintained by providers for modernized technology solutions? Are there any steps that the OCC could take to help ease or incentivize the process? For example, are community banks concerned that they may face increased regulatory scrutiny if they seek to convert their data? Alternatively, are there specific examples of regulatory relief, safe-harbors, or tailoring that the OCC could provide that may help community banks offset the capital costs of doing so?

8. Are there specific tools or training that the OCC could provide or facilitate to assist community bankers in developing their technological expertise to better manage innovation, whether internally or in managing their core service provider or other essential third-party service provider relationships?

9. Are there actions that the OCC could or should take to facilitate community banks in developing their own technology solutions? For example, are there actions that the OCC should consider to encourage and enable community banks to pursue joint ventures or to invest in subsidiaries for the purpose of developing their own innovative technology solutions?

10. What have been community banks' experiences and challenges concerning the ability to connect different third-party or in-house solutions with their core service provider? What barriers do community banks face when trying to establish API requests between core service providers and other service providers? How might the OCC address these barriers?

11. What cyber security related challenges do community banks face in connection with service providers and API requests? How do those challenges impact the ability to scale business? How do core service providers enable community banks to provide secure services, including where the bank provides services through or in connection with a non-core service

⁷ See, e.g., Financial Stability Oversight Council, *2024 Annual Report* (Dec. 6, 2024) at 88 ("Smaller firms, such as community banks and credit unions, may have lesser negotiating power to obtain certain contractual rights, fewer resources and ability to conduct due diligence on and monitor a service provider's practices (e.g., information security, internal controls, assurance testing), and lesser ability to terminate and substitute services in case of operational challenges. And yet, due to their relatively small size, these institutions are increasingly relying on third parties for essential lending, compliance, technology, and operational-related matters. Regulators and market participants alike can have low visibility into the use of common third-party service providers by financial institutions, or even the geographic location for the delivery of services. This opacity can make it difficult to prepare for, and rapidly evaluate the impact of, a cyber incident or other disruption at a third-party service provider or in a geographic location (such as a regional outage).").

⁸ See 12 U.S.C. 1867(c). Additionally, the OCC is concerned about the reported prevalence of billing errors, as well as the use of overly-complicated and lengthy billing statements that require considerable bank resources to understand and review. Billing for a service is an inherent component of performing a bank service and may be subject to supervision and regulation. The agency also notes that billing errors may expose core service providers to contractual liability and could constitute a violation of law.

provider third-party? How might the OCC address these challenges or further support core service providers enabling the provision of secure services?

Due Diligence & Transparency

12. To what extent could some of the concerns voiced by community banks discussed in this RFI be addressed by the OCC establishing a publicly searchable database related to banks' experiences with core service providers and other essential third-party service providers, including, for example, as to complaints? For example, to what extent could the existence of such a database assist community banks in performing due diligence in selecting a core service provider or other essential third-party service provider that best meets their business needs? To what extent would such a database be likely to incentivize core service providers and other essential third-party service providers to increase transparency as to opaque pricing or contracting practices or to ensure billing accuracy?

13. To what extent could some of the concerns raised in this RFI be addressed by the OCC proactively sharing with community banks certain information on core service providers and other essential service providers, including on the terms of the services they perform? What information would community banks find helpful in the planning, due diligence and third-party selection, contract negotiation, ongoing monitoring, or termination phases of the third-party risk management cycle? How should any publication be balanced against, and what steps should the agency consider regarding, the potential confidentiality of any such data or data security concerns (e.g., conditioning the provision of such data on non-disclosure agreements and the use of secure, read-only software)?

14. As an example of the above, to what extent would it assist community banks with contract negotiations if the OCC were to explore the feasibility of developing a "registry" system in which core service providers and other essential third-party service providers would be required to provide certain information to the OCC and if some or all of this information were then made available to community banks? For example, the registry system could be premised on such service providers ensuring, on a recurring basis, that their notifications to the OCC about service relationships with OCC-regulated banks remain current and include the terms of the performance of the associated services and the use of certain terms and conditions in contracts. What

considerations should the OCC evaluate if it were to adopt this approach?

15. What should constitute fair contracting terms for core service provider and other essential third-party service provider contracts with community banks? How might the OCC help ensure that such service provider agreements provide equal access to financial services, including fair treatment of community banks as customers of service providers? Should the OCC explore the feasibility of certifying whether service providers include fair contracting terms in their service agreements? What considerations should the OCC evaluate if it were to adopt this approach?

16. What challenges do community banks face when seeking to assess the financial condition of potential core service providers and other essential third-party service providers? Is there nonpublic financial information community banks believe they need to evaluate the long-term viability of such service providers? Are community banks able to negotiate access to relevant financial information of such a service provider as part of the contract deliberation process? How might the OCC assist community banks in obtaining relevant financial information to make informed decisions about engaging such service providers?

17. Should the OCC consider exploring ways to make applicable core service provider and other essential third-party service provider reports of examination (ROEs) (or targeted information obtained from the ROEs) accessible to OCC-regulated banks as they are conducting their due diligence into such service providers, before a contract is executed? To what extent would providing community banks with access to the open portion of such historical ROEs or else the latest ROEs for applicable core service providers or other essential third-party service providers give banks additional insight into whether such service providers adequately meet the banks' needs before entering into a contractual relationship? How might the provision of such ROEs to community banks impact the service provider market and the availability of services for community banks? What steps should the agency consider regarding the confidentiality of any such data or data security concerns (e.g., conditioning the provision of such data on non-disclosure agreements and the use of secure, read-only software)? What other concerns should the agency consider in operationalizing such a process?

18. To what extent do community banks utilize the ROEs for core service

providers or other essential third-party service providers with whom they have an ongoing contractual relationship as a data point in their ongoing monitoring of such service providers? Are there any challenges in using ROEs that the OCC should consider addressing (e.g., the frequency with which ROEs are issued or the content that is accessible for banks to review)? What other mechanisms should the OCC consider by which it could inform community banks about concerns related to specific core service providers or other essential third-party service providers?

Reducing Supervisory and Regulatory Burden

19. To what extent do current supervisory practices, policies, or guidance or the agency's regulations present challenges or undue burdens to community banks in managing and overseeing their core service provider relationship or in undertaking a core conversion? For example, are there elements of either the TPRM Guidance⁹ or the OCC's Third-Party Risk Management: A Guide for Community Banks¹⁰ that community banks believe to be overly prescriptive or not sufficiently clarified as being a tool to help banks assess and manage risks through practices tailored to the degree of risk present, or that community banks have experienced examiners using in a prescriptive, non-risk-based manner? Alternatively, to what extent would community banks benefit from additional supervisory or regulatory clarity?

20. To what extent has supervisory scrutiny prevented a community bank from undergoing a core conversion or in some other manner modernizing or leveraging data for innovative solutions, or materially increased the burden on a community bank going through such a process? Are there examples of supervisory or regulatory reform, tailoring, or safe harbors that could allow the agency to better facilitate core conversions or data ownership and modernization that a community bank believes is in the best interest of its business while not downplaying the

⁹ The OCC reiterates that the TPRM Guidance is intended to be a principles-based tool for banks to assess and manage their risks from third parties. It is not a prescriptive requirement and a bank's third-party risk management should be tailored to the bank's size, complexity, and risk profile and to the nature of its third-party relationships. See also 12 CFR part 4, subpart F (Use of Supervisory Guidance).

¹⁰ May 2024, available at: <https://www.occ.gov/news-issuances/news-releases/2024/pub-third-party-risk-management-guide-for-community-banks.pdf>.

safety and soundness risks inherent in such practices?

Costs

21. How has the cost of contracting with core service providers or other essential third-party service providers evolved over the last ten years? How have these changes impacted the ability of community banks to modernize operations? How can such service providers and community banks address challenges posed by rising costs? What role might the OCC be able to serve in addressing concerns and challenges posed by costs?

22. To what extent have costs prevented conversions or impacted the abilities of community banks to modernize operations? Are such costs imposed by service providers, related to internal factors (e.g., deficiencies in staffing resources or expertise), or due to supervisory or regulatory scrutiny or requirements? What role might the OCC be able to serve in addressing these concerns?

23. How would any of the policies contemplated in this RFI affect costs and the availability of services from core service providers and other essential third-party service providers?

24. What data should community banks, core service providers and other essential third-party service providers, or the OCC consider when evaluating such service providers' costs?

25. To what extent has a service provider's systems or operations created legal risk or caused any violations of laws or regulations for the bank?

Billing Statements and Errors

26. To what extent are community banks able to timely and effectively review billing statements from core service providers or other essential third-party service providers? What challenges do community banks face in reviewing these billing statements, including as to length and complexity? What resources do community banks need to dedicate to reviewing these billing statements?

27. To what extent have community banks experienced errors in core service providers' or other essential third-party service providers' billing statements? What is the average frequency and what are the average dollar values (including in absolute terms and as a percentage of the entire bill) of any such errors? What is the impact of such errors on the bank?

28. How might the OCC (together with the Board of Governors of the Federal Reserve System and the Federal Deposit Insurance Corporation, as part of their joint service provider examinations) better reflect the prevalence of core

service providers' or other essential third-party service providers' billing practices and errors in any applicable service providers' examination ratings?

29. To what extent would a database (discussed in Question 12 above) help address the prevalence of any such billing errors?

30. To what extent would guidance on core service provider and other essential third-party service provider billing and fee best practices and supervisory expectations help address the prevalence of any such billing errors?

31. What other actions should the OCC consider taking in addressing any prevalent billing errors?

Facilitating Community Bank and Service Provider Dialogue

32. Prior to the pandemic, the OCC held annual meetings with various core service provider and other essential third-party service provider executives. To what extent would reviving those annual meetings or otherwise establishing contact channels help facilitate the sharing of community bank concerns with such service providers?

33. What would be the benefits and challenges of the OCC facilitating community banks and other interested parties in establishing ad hoc or standing groups that could work towards planning and implementing private market solutions to any of the concerns addressed in this RFI?

Jonathan V. Gould,

Comptroller of the Currency.

[FR Doc. 2025-21333 Filed 11-26-25; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Revision of an Approved Information Collection; Comment Request; Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions With Total Consolidated Assets of \$250 Billion or More Under the Dodd-Frank Wall Street Reform and Consumer Protection Act

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork

Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning a revision to its information collection titled "Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of \$250 Billion or More under the Dodd-Frank Wall Street Reform and Consumer Protection Act."

DATES: Comments must be received by January 27, 2026.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- **Email:** prainfo@occ.treas.gov.
- **Mail:** Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557-0319, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- **Hand Delivery/Courier:** 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

• **Fax:** (571) 293-4835.
Instructions: You must include "OCC" as the agency name and "1557-0319" in your comment. In general, the OCC will publish comments on www.reginfo.gov without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

• **Viewing Comments Electronically:** Go to www.reginfo.gov. Hover over the "Information Collection Review" tab and click on "Information Collection Review" from the drop-down menu. From the "Currently under Review" drop-down menu, select "Department of

Treasury” and then click “submit.” This information collection can be located by searching OMB control number “1557–0319” or “Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of \$250 Billion or More under the Dodd-Frank Wall Street Reform and Consumer Protection Act.” Upon finding the appropriate information collection, click on the related “ICR Reference Number.” On the next screen, select “View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel’s Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 generally requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the revision of this collection.

Title: “Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of \$250 Billion or More under the Dodd-Frank Wall Street Reform and Consumer Protection Act.”

OMB Control No.: 1557–0319.

Type of Review: Revision.

Affected Public: Businesses or other for-profit.

Description: Section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act¹ (Dodd-Frank

Act) requires certain financial companies, including national banks and Federal savings associations, to conduct periodic stress tests² and requires the primary financial regulatory agency³ of those financial companies to issue regulations implementing the stress test requirements.⁴ Under section 165(i)(2), a covered institution is required to submit to the Board of Governors of the Federal Reserve System (Board) and to its primary financial regulatory agency a report at such time, in such form, and containing such information as the primary financial regulatory agency may require.⁵

On October 9, 2012, the OCC published in the **Federal Register** a final rule implementing the section 165(i)(2) annual stress test requirement.⁶ This rule describes the reports and information collections required to meet the reporting requirements under section 165(i)(2). These information collections will be treated as confidential (to the extent permitted by law).⁷

In 2012, the OCC first implemented the reporting templates referenced in the final rule,⁸ and the OCC is now proposing revisions to these templates. The OCC uses the data collected to assess the reasonableness of the stress test results of covered institutions and to provide forward-looking information to the OCC regarding a covered institution’s capital adequacy. The OCC also may use the results of the stress tests to determine whether additional analytical techniques and exercises could be appropriate to identify, measure, and monitor risks at the covered institution. The stress test results are expected to support ongoing improvement in a covered institution’s stress testing practices with respect to its internal assessments of capital adequacy and overall capital planning.

The OCC recognizes that many covered institutions with total consolidated assets of \$250 billion or more are required to submit reports using reporting form FR Y–14A.⁹ The OCC also recognizes the Board has proposed, but not finalized, modifications to the FR Y–14A and, to the extent practical, the OCC is keeping its reporting requirements consistent

with the Board’s FR Y–14A in order to minimize burden on covered institutions.¹⁰

The OCC’s proposed changes include only limited updates, and the OCC reporting forms will substantially resemble the forms used by the OCC last year. The OCC’s changes generally parallel the Board’s changes, including modifications to collect additional information of a covered institution’s pre-provision net revenue. The OCC’s revisions also include removing some items.

If the Board proposes additional changes to the FR Y–14A reporting forms after the publication of this notice, the OCC may make corresponding changes to the OCC reporting forms to minimize inconsistencies and reduce burden. The OCC’s revised reporting forms and instructions are available on the OCC’s website at <https://www OCC.treas.gov/publications-and-resources/forms/dodd-frank-act-stress-test/index-dodd-frank-act-stress-test.html>.

Estimated Burden:

Estimated Frequency of Response: On occasion.

Estimated Number of Respondents: 4 annually and 5 biennially.

Estimated Total Annual Burden: 3,990 hours.

Comments submitted in response to this notice will be summarized and 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 OCC, including whether the information has practical utility;

(b) The accuracy of the OCC’s estimate of the burden of the collection of information;

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

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Eden Gray,

Assistant Director, Office of the Comptroller of the Currency.

[FR Doc. 2025–21317 Filed 11–26–25; 8:45 am]

BILLING CODE 4810–33–P

² 12 U.S.C. 5365(i)(2)(A).

³ 12 U.S.C. 5301(12).

⁴ 12 U.S.C. 5365(i)(2)(C).

⁵ 12 U.S.C. 5365(i)(2)(B).

⁶ 77 FR 61238 (October 9, 2012) (codified at 12 CFR part 46).

⁷ 5 U.S.C. 552(b)(4).

⁸ See 77 FR 49485 (August 16, 2012) and 77 FR 66663 (November 6, 2012).

⁹ <http://www.federalreserve.gov/reportforms>.

¹⁰ 90 FR 16843 (April 22, 2025).

¹ Public Law 111–203, 124 Stat. 1376, July 2010.

DEPARTMENT OF THE TREASURY**Bureau of the Fiscal Service****Extension of a Currently Approved Information Collection: Application Forms for U.S. Department of the Treasury Stored Value Card (SVC) Program**

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. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Application Forms for U.S. Department of the Treasury Stored Value Card (SVC) Program.

DATES: Written comments should be received on or before January 27, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006-A, P.O. Box 1328, Parkersburg, WV 26106-1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Application Forms for U.S. Department of the Treasury Stored Value Card (SVC) Program.

OMB Number: 1530-0013.

FS Form 2887—Application Forms for U.S. Department of the Treasury Stored Value Card (SVC) Program; FS Form 2889—U.S. Department of the Treasury Stored Value Card Contractor Agreement; and FS Form 5752—Authorization To Disclose Information Related To Stored Value Account.

Abstract: This collection of forms is used to collect information from individuals requesting enrollment in the Treasury SVC program along with supplemental information for contractors choosing to participate in the program, to obtain authorization to initiate debit and credit entries to their bank or credit union accounts, and to facilitate collection of any delinquent amounts. Disclosure of the information requested on the forms is voluntary; however, failure to furnish the requested information may significantly delay or prevent participation in the Treasury SVC program.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or households.

Estimated Number of Respondents: 102,030.

Estimated Time per Respondent: 10 minutes for FS Form 2887 and FS Form 2889; 1 minute for FS Form 5752.

Estimated Total Annual Burden Hours: 17,001.

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: 1. 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; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. 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 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 25, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025-21518 Filed 11-26-25; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF THE TREASURY**Bureau of the Fiscal Service****Extension of a Currently Approved Information Collection: Request To Reissue United States Savings Bonds**

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. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Request to Reissue United States Savings Bonds.

DATES: Written comments should be received on or before January 27, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006-A, PO Box 1328, Parkersburg, WV 26106-1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Request to Reissue United States Savings Bonds.

OMB Number: 1530-0025.

Form Number: FS Form 4000.

Abstract: The information is requested to support a request to reissue paper (definitive) Series EE and Series I United States Savings Bonds; Retirement Plan Bonds; and Individual Retirement Plan Bonds and to indicate the new registration required.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 38,000.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 19,000.

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: 1. 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; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. 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 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 25, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025-21521 Filed 11-26-25; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF THE TREASURY**Bureau of the Fiscal Service****Extension of a Currently Approved Information Collection: Electronic Funds Transfer (EFT) Market Research Study**

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. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Electronic Funds Transfer (EFT) Market Research Study.

DATES: Written comments should be received on or before January 27, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Electronic Funds Transfer (EFT) Market Research Study.

OMB Number: 1530–0022.

Form Number: None.

Abstract: This is a generic clearance to conduct customer satisfaction surveys, focus groups, and interviews among recipients of federal benefit and vendor payments through EFT. The need for this market research continues to arise from a Congressional directive that accompanied legislation enacted in 1996, as part of the Debt Collection Improvement Act (Pub. L. 104–134), expanding the scope of check recipients required to use direct deposit to receive Federal benefit payments (see 31 U.S.C. 3332). Congress directed Treasury to “study the socioeconomic and demographic characteristics of those who currently do not have Direct Deposit and determine how best to increase usage among all groups.” 142 Cong. Rec. H4090 (daily ed. April 25, 1996).

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or households, Federal Government.

Estimated Number of Respondents: 19,500.

Estimated Time per Respondent: 16 minutes.

Estimated Total Annual Burden Hours: 5,200.

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: 1. 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; 2. the accuracy of the agency’s estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. 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 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 25, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025–21520 Filed 11–26–25; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY**Bureau of the Fiscal Service****Extension of a Currently Approved Information Collection: Application Form for U.S. Department of the Treasury Accountable Official Stored Value Card (SVC) Program**

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. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Application Form for U.S. Department of the Treasury Accountable Official Stored Value Card (SVC) Program.

DATES: Written comments should be received on or before January 27, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328,

Parkersburg, WV 26106–1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Application Form for U.S. Department of the Treasury Accountable Official Stored Value Card (SVC) Program.

OMB Number: 1530–0020.

Form Number: FS Form 2888.

Abstract: This form is used to collect information from accountable officials requesting enrollment in the Treasury SVC program in their official capacity, to obtain authorization to initiate debit and credit entries to their bank or credit union accounts, and to facilitate collection of any delinquent amounts that may become due and yet to be paid as a result of the use of the cards.

This information is collected under the authority in: 31 U.S.C. 321, General Authority of the Secretary of the Treasury; Public Law 104–134, Debt Collection Improvement Act of 1996, as amended; Department of Defense Financial Management Regulation (DoDFMR) 7000.14–R, as amended; 5 U.S.C. 5514, Installment deduction for indebtedness to the United States; 31 U.S.C. 1322, Payments of unclaimed trust fund amounts and refund of amounts erroneously deposited; 31 U.S.C. 3720, Collection of payments; 31 U.S.C. 3720A, Reduction of tax refund by amount of debt; 31 U.S.C. 7701, Taxpayer identifying number; 37 U.S.C. 1007, Deductions from pay; 31 CFR part 210, Federal Government Participation in the Automated Clearing House; 31 CFR part 285, Debt Collection Authorities under the Debt Collection Improvement Act of 1996; and E.O. 9397 (SSN), as amended.

The information on this form may be disclosed as generally permitted under 5 U.S.C. 552(a)(b) of the Privacy Act of 1974, as amended. It may be disclosed outside of the U.S. Department of the Treasury to its Fiscal and Financial Agents and their contractors involved in providing SVC services, or to the Department of Defense (DoD) for the purpose of administering the Treasury SVC programs. In addition, other Federal, State, or local government agencies that have identified a need to know may obtain this information for the purpose(s) as identified by Fiscal Service’s Routine Uses as published in the **Federal Register**.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 7,500.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 1,250.

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: 1. 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; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. 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 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 25, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025–21519 Filed 11–26–25; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Extension of a Currently Approved Information Collection: Description of United States Savings Bonds Series HH/H and Description of United States Bonds/Notes

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. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Description of United States Savings Bonds Series HH/H and Description of United States Bonds/Notes.

DATES: Written comments should be received on or before January 27, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A.

Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or bruce.sharp@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

Title: Description of United States Savings Bonds Series HH/H and Description of United States Bonds/Notes.

OMB Number: 1530–0037.

Form Number: FS Form 1980; and FS Form 2490.

Abstract: The information collected is necessary to obtain information describing an owner's holding of United States Securities.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 950.

Estimated Time per Respondent: 6 minutes.

Estimated Total Annual Burden Hours: 95.

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: 1. 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; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. 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 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 25, 2025.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2025–21522 Filed 11–26–25; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on U.S. Withholding Tax Return for Disposition by Foreign Persons of U.S. Real Property Interests and Statement of Withholding on Dispositions by Foreign Persons of U.S. Real Property Interests

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before January 27, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include “OMB Control No. 1545–0902” in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

View the latest drafts of the tax forms related to the information collection listed in this notice at <https://www.irs.gov/draft-tax-forms>. Requests for additional information or copies of this collection should be directed to Kerry Dennis, (202) 317–5751.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity

of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: U.S. Withholding Tax Return for Disposition by Foreign Persons of U.S. Real Property Interests and Statement of Withholding on Dispositions by Foreign Persons of U.S. Real Property Interests.

OMB Control Number: 1545–0902.

Form Number: Form 8288, Form 8288–A and Form 8288–C.

Abstract: Internal Revenue Code section 1445 requires transferees to withhold tax on the amount realized from sales or other dispositions by foreign persons of U.S. real property interests. Form 8288 is used to report and transmit the amount withheld to the IRS. Form 8288–A is used by the IRS to validate the withholding, and a copy is returned to the transferor for his or her use in filing a tax return. Information provided in § 1.1446(f)–3(d) by the partnership to the IRS will be used by the partnership to report and pay any tax under section 1446(f)(4) and § 1.1446(f)–3 and will be provided on Form 8288–C.

Current Actions: Revisions to the Form 8288 were made to comply with Executive Order 14247, that requires every payment from the IRS to be eligible for direct deposit. The revision to the form is not substantively changing the use of the form or the data being collected. There have been no changes to Form 8288–A or Form 8288–C.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals or households.

Estimated Number of Responses: 237,500.

Estimated Time per Response: 9 hours, 50 minutes.

Estimated Total Annual Burden Hours: 2,334,750.

Dated: November 19, 2025.

Kerry Dennis,
Tax Analyst.

[FR Doc. 2025–21412 Filed 11–26–25; 8:45 am]

BILLING CODE 4830–01–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: December 3, 2025, 10:00 a.m. to 1:00 p.m., MST.

PLACE: This meeting will take place at the Embassy Suites by Hilton Scottsdale Resort, 5001 North Scottsdale Road, Scottsdale, Arizona 85250. The meeting will also be accessible via conference call and via Zoom Meeting and Screenshot. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 981 6246 4632, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshot is <https://kellen.zoom.us/j/98162464632>.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the “Board”) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Welcome and Call to Order—UCR Board Chair

The UCR Board Chair will welcome attendees, call the meeting to order, call roll for the Board, confirm the presence of a quorum, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify publication of the meeting notice on the UCR website and distribution to the UCR contact list via email, followed by subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Board Agenda—UCR Board Chair

For Discussion and Possible Board Action

The proposed Agenda will be reviewed. The Board will consider action to adopt.

Ground Rules

➤ Board actions taken only in designated areas on the agenda

IV. Approval of Minutes of the October 30, 2025, UCR Board Meeting—UCR Board Chair

For Discussion and Possible Board Action

Draft Minutes from the October 30, 2025, UCR Board meeting will be reviewed. The Board will consider action to approve.

V. Report of FMCSA—FMCSA Representative

The Federal Motor Carrier Safety Administration (FMCSA) will provide a report on any relevant agency activity.

VI. Presentation of Proposed Contract with DSL Transportation Services, Inc.—UCR Board Chair and Executive Director

For Discussion and Possible Board Action

The UCR Board Chair and Executive Director will present a proposed contract between the UCR Plan and DSL Transportation Services, Inc., with a 1-year term for the Board’s consideration. The Board may take action to approve a contract with DSL Transportation Services, Inc., under the terms and conditions discussed and approved by the Board.

VII. Subcommittee Reports

Audit Subcommittee—UCR Audit Subcommittee

No report.

Dispute Resolution Subcommittee—UCR Dispute Resolution Subcommittee Chair

No report.

Education and Training Subcommittee—UCR Education and Training Subcommittee Chair

The UCR Education and Training Subcommittee Chair will provide an update on key projects and initiatives, including the ongoing development of the learning management program and training modules, awareness and engagement efforts for various stakeholders, and the optimization of the website and newsletter.

Enforcement Subcommittee—UCR Enforcement Subcommittee Chair

The UCR Enforcement Subcommittee Chair will provide an update on current and planned initiatives, including efforts to enhance UCR enforcement efficiency, and recognition of states and inspectors.

Finance Subcommittee—UCR Finance Subcommittee Chair and UCR Depository Manager

A. 2024 External Financial Audit Update—UCR Finance Subcommittee Chair and UCR Depository Manager

The UCR Finance Subcommittee Chair and UCR Depository Manager will provide an update on the UCR Plan's 2024 External Financial Audit.

B. Management Report—UCR Finance Subcommittee Chair and UCR Depository Manager

The UCR Finance Subcommittee Chair and UCR Depository Manager will provide an update on UCR finances and related topics.

Industry Advisory Subcommittee—UCR Industry Advisory Subcommittee Chair

No report.

VIII. Contractor Reports—UCR Board Chair

UCR Executive Director Update

The UCR Executive Director will provide a report covering his recent activity for the UCR Plan.

UCR Administrator Update (Kellen)

The UCR Chief of Staff will provide a management update covering any additional activity for the Depository, Operations, and Communications.

DSL Transportation Services, Inc.

DSL Transportation Services, Inc. will report on the latest data from the FARs program, Tier 5 and 6 unregistered motor carriers, and other matters.

Seikosoft

Seikosoft will provide an update on its recent/new activity related to the UCR's National Registration System.

IX. Chief Legal Officer Report—UCR Chief Legal Officer

The UCR Chief Legal Officer will provide a report covering the status of

several legal issues involving the UCR Plan.

X. Other Business—UCR Board Chair

The UCR Board Chair will call for any other business, old or new, from the floor.

XI. Adjournment—UCR Board Chair

The UCR Board Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern daylight time, November 21, 2025, at: <https://plan.ucr.gov>.

CONTACT PERSON FOR MORE INFORMATION:

Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305-3783, eleaman@board.ucr.gov.

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2025-21497 Filed 11-25-25; 4:15 pm]

BILLING CODE 4910-YL-P

DEPARTMENT OF VETERANS AFFAIRS

[Docket No. VA-2025-VACO-0002]

Enhanced-Use Lease of Department of Veterans Affairs Real Property for the Development of Permanent Supportive Housing at the Kerrville Veterans Affairs Medical Center, Kerrville, Texas Campus

AGENCY: Department of Veterans Affairs.

ACTION: Notice of intent to enter into an enhanced-use lease.

SUMMARY: The Secretary, Department of Veterans Affairs (VA), intends to enter into an Enhanced-Use Lease (EUL) on approximately three acres of underutilized land on the campus of the Kerrville, Texas VA Medical Center.

FOR FURTHER INFORMATION CONTACT: C. Brett Simms, Executive Director, Office of Asset Enterprise Management, (202) 502-0262.

SUPPLEMENTARY INFORMATION: Pursuant to 38 U.S.C. 8161, *et seq.* as amended by Public Law 117-168, the Secretary of VA is authorized to enter into an EUL for a term consistent with that section, that (a) provides supportive housing for veterans and their families, or (b) enhances the use of the leased property by directly or indirectly benefitting veterans. In addition, the EUL must not be inconsistent with and not adversely affect VA's mission or the operation of VA's facilities, programs, and services in the area of the leased property.

Consistent with this authority, the Secretary intends to enter into an EUL for the purpose of outleasing approximately three acres of underutilized land on the campus of the Kerrville, Texas VA Medical Center, to develop approximately 52 units of permanent supportive housing for veterans and their families. The competitively selected EUL lessee/developer, Freedom's Path Kerrville II, Limited Partnership, will finance, design, develop, renovate, construct, manage, maintain, and operate housing for eligible homeless veterans or veterans at risk of homelessness on a priority placement basis. In addition, the lessee/developer will be required to provide supportive services that guide veteran residents towards long-term independence and self-sufficiency.

Signing Authority

Douglas A. Collins, Secretary of Veterans Affairs, approved this document on November 24, 2025, 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.

Taylor N. Mattson,

Alternate Federal Register Liaison Officer, Department of Veterans Affairs.

[FR Doc. 2025-21365 Filed 11-26-25; 8:45 am]

BILLING CODE 8320-01-P



FEDERAL REGISTER

Vol. 90

Friday,

No. 227

November 28, 2025

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS-4212-P]

RIN 0938-AV63

Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), and Medicare cost plan regulations to implement changes related to Star Ratings, marketing and communications, drug coverage, enrollment processes, special needs plans, and other programmatic areas.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Time on January 26, 2026.

ADDRESSES: In commenting, please refer to file code CMS-4212-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4212-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4212-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Kristy Nishimoto, (206) 615-2367—General Questions and Beneficiary Enrollment Issues.

Naseem Tarmohamed, (410) 786-0814—Part C and Cost Plan Issues.

Lucia Patrone, (410) 786-8621—Part D Issues.

Alissa Stoneking, (410) 786-1120—Parts C and D Payment Issues.

Sara Klotz, (410) 786-1984—D-SNP Issues.

Beckie Peyton, (410) 786-1572—Manufacturer Discount Program Issues.

PartCandDStarRatings@cms.hhs.gov—Parts C and D Star Ratings Issues.

CMMI_MAStrategy@cms.hhs.gov—RFI on Future Directions in Medicare Advantage.

CPI_PartC&D_RegIssues@cms.hhs.gov—Part D Program Integrity Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all 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>. Follow the search instructions on that website to view public comments. CMS 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 an individual. CMS continues to encourage 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.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at <https://www.regulations.gov/>.

Deregulation Request for Information (RFI): On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 “Unleashing Prosperity Through Deregulation,” which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality

of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. We have made available an RFI at <https://www.cms.gov/medicare-regulatory-relief-rfi>. Please submit all comments in response to this request for information through the provided weblink. Please note, this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency’s full consideration, are not generally considered information collections and therefore not subject to the PRA.

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, and Medicare cost plan program. This proposed rule includes a number of changes that would improve these programs for contract year 2027 as well as codify existing sub-regulatory guidance.

We note that, as with previous rules, the new marketing and communications policies in this rule are proposed to be applicable for all contract year 2027 marketing and communications, beginning October 1, 2026.

B. Summary of the Key Provisions

1. Medicare Part D Redesign

This proposal would implement the changes made to the Part D benefit design and the payment obligations of enrollees, Part D plan sponsors, manufacturers, and CMS by section 11201 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169).

We are proposing to codify the statutory changes to the phases of the Part D benefit made by the IRA related to the deductible, initial coverage limit, the coverage gap, the annual out-of-pocket threshold, and alternative prescription drug coverage options. In alignment with these changes to the Part

D benefit, we are also proposing to codify technical and conforming changes to our specialty tier regulations. This proposal would codify additional structural and operational statutory changes to the Part D benefit design, including making changes to the types of payments that count as True Out-Of-Pocket costs (TrOOP), establishing a policy for how an enrollee's costs for drugs not subject to the Part D defined standard deductible count towards becoming eligible for manufacturer discounts under the Medicare Part D Manufacturer Discount Program (Manufacturer Discount Program), making updates to the methodology for reinsurance payments from us to Part D sponsors, and implementing the Selected Drug Subsidy, among others.

2. Coverage Gap Discount Program

We propose to codify the sunset of the Coverage Gap Discount Program and termination of all Coverage Gap Discount Program agreements as of January 1, 2025, in alignment with subsection (h) of section 1860D–14A of the Social Security Act (the Act), as added by section 11201 of the IRA. Specifically, we propose to revise § 423.2300 by adding paragraph (b) to establish applicability dates for the Coverage Gap Discount Program, revise § 423.2345 by adding paragraph (f) to terminate all Coverage Gap Discount Program agreements, as well as make conforming changes for clarity.

3. Manufacturer Discount Program

We propose regulatory changes to codify the Manufacturer Discount Program, established in section 1860D–14C of the Act, as added by section 11201 of the IRA. Under the Manufacturer Discount Program, which replaces the Coverage Gap Discount Program and began on January 1, 2025, manufacturers that enter into a Manufacturer Discount Program agreement are required to provide

discounts on applicable drugs in both the initial and catastrophic coverage phases of the Part D benefit. Specifically, we propose to add new subpart AA to part 423 to codify the Manufacturer Discount Program requirements and make several conforming changes throughout part 423 to reflect the new program.

4. Updates to Star Ratings

We have continued to identify enhancements to the Star Ratings program over time to increase the health and wellbeing of enrollees. In this proposed rule, we are proposing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set. We also propose to not move forward with the implementation of the Health Equity Index (also called Excellent Health Outcomes for All) reward at §§ 422.166(f)(3) and 423.186(f)(3) and to continue to include the historical reward factor in the Star Ratings methodology at §§ 422.166(f)(1) and 423.186(f)(1). We also solicit comments on ways to further simplify and modify the Star Ratings program to further drive improved quality of care and reduce regulatory burden.

5. Request for Information on Dually Eligible Individual Enrollment Growth in C–SNPs and I–SNPs

Chronic condition special needs plans (C–SNPs) and the number of dually eligible individuals enrolled in these plans have grown significantly between 2021 and 2025. Dually eligible enrollment in institutional special needs plans (I–SNPs) has remained more stable. While C–SNPs and I–SNPs can offer benefits specific to chronic disease and institutional level of care, respectively, they do not integrate Medicare and Medicaid benefits and may not be the best approach for meeting the needs of dually eligible individuals. The growth in C–SNP

enrollment could be an intentional approach by MA organizations to circumvent Federal and State requirements for dual eligible special needs plans (D–SNPs), such as States determining which D–SNPs will be offered in a State through their State Medicaid agency contract authority and general coordination and integration requirements. This proposed rule includes a request for information (RFI) to share information with interested parties on these trends and solicit feedback on them as well as on potential policy solutions for future consideration.

6. Request for Information on Future Directions in Medicare Advantage (Risk Adjustment and Quality Bonus Payments)

This RFI will serve as a formal mechanism to solicit comprehensive public input from interested parties, including MA organizations, beneficiary advocates, healthcare providers, as well as technology and industry experts, regarding the future direction of the MA program. The goal of this RFI is to solicit comment on modernizing and improving the MA program that could be implemented through either programmatic changes or through a CMS Innovation Center (CMMI) model. This public comment process will enable us to gather critical feedback on risk adjustment enhancements and quality bonus payment changes. Through this RFI, we are working to ensure any resulting changes would effectively address interested parties' concerns while achieving objectives of data transparency for beneficiaries to facilitate optimal plan selection, improved quality, enhanced competition, taxpayer savings, and minimizing fraud, waste, and abuse in the MA program.

C. Summary of Costs and Benefits

BILLING CODE 4120–01–P

TABLE A1: SUMMARY OF PROVISIONS AND FINANCIAL IMPACTS

Provision	Description	Financial Impact
Medicare Part D Redesign	We are proposing to codify the changes made to the Part D benefit design by section 11201 of the IRA. This includes our proposal to codify the sunset of the Coverage Gap Discount Program as of January 1, 2025, under section 1860D-14A(h) of the Act and our proposal to codify policies for the Manufacturer Discount Program beginning January 1, 2025, under section 1860D-14C of the Act.	Relative to a pre-statute baseline, codifying the statutory changes to the Part D benefit design would increase costs. The costs and transfers attributable to the Part D redesign are attributable to the IRA and are not a result of this rule.
Updates to Star Ratings	We are proposing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set and not moving forward with the implementation of the Health Equity Index reward and to continue to include the historical reward factor in the Star Ratings methodology.	The net impact of the Star Ratings updates to the Medicare Trust Fund is estimated to be \$13.18 billion from 2027 through 2036 or 0.15 percent of Medicare payments to private health plans during this ten year period.
RFI on Dually Eligible Individual Enrollment Growth in C-SNPs and I-SNPs	We are outlining data on C-SNP and I-SNP enrollment trends for dually eligible individuals and solicit comments on potential policy considerations for future rulemaking.	None
RFI on Future Directions in Medicare Advantage	We are seeking public input on future directions for the MA program to address risk adjustment and quality bonus payment changes that could be implemented either through programmatic changes at large or through a CMS Innovation Center model.	None

BILLING CODE 4120-01-C

D. Supplemental Requests for Information

We are requesting comments on several specific areas beyond the various comment opportunities already presented throughout the proposed rule as part of our commitment to reducing regulatory burden while strengthening program integrity. First, we are considering ways to modernize our approach to marketing oversight and agent/broker regulation in the Medicare program while ensuring beneficiaries continue to receive accurate information about plan choices. This includes, but is not limited to, all of the following:

- Modifying the current definition of third-party marketing organization (TPMO) under §§ 422.2260 and 423.2260 to delineate the roles of and requirements applicable to the different kinds of TPMOs.
- Modifying the 5 percent translation requirement found in §§ 422.2267 and 423.2267.
- Removing the requirement for our approval of plan use of the Medicare Card image found in §§ 422.2262(a)(1)(xix) and 423.2262(a)(1)(xviii).
- Eliminating the Outbound Enrollment Verification found in §§ 422.2272(b) and 423.2272(b).
- Modifying testimonial requirements found under §§ 422.2262(b) and 423.2262(b).
- Eliminating mailing statement requirements found under §§ 422.2267(e)(36) and 423.2267(e)(37).

We are also looking specifically at regulatory changes that will assist the agency in taking appropriate action against TPMOs, including agents and brokers who fail to adhere to our requirements. Our goal is to address non-compliance, holding MA plans and Part D sponsors accountable for those TPMOs who provide inaccurate, misleading, and confusing information, or act in a manner contrary to our requirements. We have considered options such as further segmentation of the definition for TPMOs found under §§ 422.2260 and 423.2260 to account for size, scope, and role of various interested parties; however, we recognize the need for industry input before implementing any change. We, therefore, solicit comments on how to hold “bad actors” accountable, while not burdening those TPMOs and plans that adhere to our requirements. We also solicit comments on how to properly align incentives in the agent or broker space, how to identify and address when agents and brokers perform their jobs in good faith but does not adhere

to requirements that apply to the MA plan. For example, we welcome comment on whether updates to the training and testing requirements are needed or new ways CMS or MA organizations and Part D sponsors can improve how beneficiaries interact with agents or brokers. We are also soliciting comments on how best to monitor and assess the actions of MA organizations, Part D sponsors, and their downstream entities such as TPMOs, using data driven strategies. We are interested in finding ways to better utilize data—whether it is CMS, plan, first tier, downstream or related entity (FDR), or TPMO data—to review and monitor the MA and Part D market, and to assist us in addressing MA organization and PDP sponsor compliance with our requirements. Likewise, the agency is also seeking interested parties feedback regarding how technology can be leveraged, including on the use of artificial intelligence, to enhance the decision support tools used by beneficiaries and their caregivers.

In addition to issues regarding marketing oversight and agent/broker regulation and consistent with the Administration’s deregulation priorities, we are seeking comment on current reporting processes and data collections to identify specific areas where requirements can be simplified, consolidated, or eliminated while maintaining program integrity and beneficiary protections in the following areas:

- Network adequacy.
- Medical loss ratio (MLR) reporting.
- Benefit, including supplemental benefit, usage and utilization data reporting.
- Requirements related to the SNP model of care (MOC).

We are interested in ideas for streamlining data collection processes for the areas listed previously, including automated data sharing to reduce manual reporting and ideas related to alignment with existing reporting mechanisms. We are also interested in feedback regarding which data elements are the most burdensome to collect and report, as we seek to balance the level of detail required to maintain proper program oversight while promoting efficiency.

Regarding network adequacy, we seek comments on how to simplify the provider and facility network review process overall, including the submission process, the exception request process, and the timing and frequency of the reviews. An example of a way that we could simplify the exception request process is to create a separate pattern of care exception under

§ 422.116(f)(1), that could be used where the pattern of care in the area is unique and the organization believes their contracted network is consistent with or better than the Original Medicare pattern of care. An organization could use this exception in lieu of demonstrating the current requirements under § 422.116(f)(1)(i), that is: (A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type ; and (B) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

We welcome comments on these topics.

E. Conclusion

Finally, we are clarifying and emphasizing our intent that if any provision of this rule, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this rule 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 propose 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 (such as by a cross-reference to apply the same standards or requirements).

II. Implementation of Certain Provisions of the Inflation Reduction Act of 2022 and the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018

*A. Medicare Part D Redesign**1. Background*

Section 11201 of the Inflation Reduction Act of 2022 (IRA) made significant changes to the Part D benefit design that affect the structure of the Part D benefit and the payment obligations of enrollees, Part D plan sponsors, manufacturers, and CMS. Several of the changes made by section 11201 of the IRA have taken effect already and other changes will go into effect in 2026, as described later.

Section 11201(f) of the IRA directed the Secretary to implement section

11201 of the IRA for 2024, 2025, and 2026 by program instruction or other forms of program guidance. On February 1, 2023, we released guidance outlining changes to the Part D benefit that were specific to Calendar Year (CY) 2024 in the CY 2024 Advance Notice and Rate Announcement.¹ In that guidance, we eliminated cost sharing for covered Part D drugs in the catastrophic phase of coverage, consistent with section 1860D–2(b)(4)(A)(i) of the Social Security Act (the Act), as amended by section 11201 of the IRA.²

On April 1, 2024, we released the Final CY 2025 Part D Redesign Program Instructions.³ In these program instructions, we implemented changes to the structure of the Part D benefit for CY 2025 made by section 11201 of the IRA. Section 11201 of the IRA added section 1860D–2(b)(4)(B)(i)(VII) of the Act to reduce the annual out-of-pocket (OOP) threshold to \$2,000 for CY 2025 (to be annually increased by the annual percentage increase, as described in section 1860D–2(b)(6) of the Act). The IRA also amended section 1860D–2(b) of the Act to eliminate the coverage gap phase and added subsection (h) to section 1860D–14A of the Act to sunset the Coverage Gap Discount Program. The IRA added section 1860D–14C of the Act to establish the Manufacturer Discount Program.

On April 7, 2025, we issued the Final CY 2026 Part D Redesign Program Instructions which described changes to the Part D benefit for CY 2026.⁴ In these program instructions, we implemented further changes made by the IRA to the Part D benefit that go into effect in CY 2026, including certain changes to the Part D benefit that relate to the Medicare Drug Price Negotiation Program that also was established by the IRA. Beginning January 1, 2026, the maximum fair prices (MFPs) negotiated under the Medicare Drug Price Negotiation Program go into effect.⁵ This program, as established in Part E of title XI of the Act, permits the Secretary to negotiate MFPs for certain high expenditure, single source drugs and biological products with participating manufacturers. When these prices go into effect, the IRA makes further

changes to payment obligations in Part D related to selected drugs (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act).

As described in the Final CY 2026 Part D Redesign Program Instructions, the defined standard Part D benefit for CY 2026 will consist of the following phases and liabilities, with the CY 2026 changes reflected in bolded and italicized font:

- *Annual deductible.* The enrollee pays 100 percent of their gross covered prescription drug costs (GCPDC) until the deductible is met.
- *Initial coverage.* The enrollee pays 25 percent coinsurance for covered Part D drugs. The Part D plan sponsor typically pays 65 percent of the costs of applicable drugs and selected drugs⁶ and 75 percent of the costs of all other covered Part D drugs. The manufacturer, through the Manufacturer Discount Program, typically covers 10 percent of the costs of applicable drugs. ***In the initial coverage phase, CMS will pay a 10 percent subsidy for selected drugs during a price applicability period.*** This phase ends when the enrollee has reached the annual OOP threshold of \$2,100 for CY 2026.
- *Catastrophic.* The enrollee pays no cost sharing for Part D drugs. Part D plan sponsors typically pay 60 percent of the costs of all covered Part D drugs. The manufacturer pays a discount, typically equal to 20 percent, for applicable drugs. Medicare pays a reinsurance subsidy equal to 20 percent of the costs of applicable drugs, and equivalent to 40 percent of the costs of all other covered Part D drugs that are not applicable drugs. ***In the catastrophic phase, Medicare will provide 40 percent reinsurance for selected drugs during a price applicability period.***

As part of the overall restructuring of the Part D benefit, the IRA also made changes to the treatment of Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines and covered insulin products under Part D. Section 11401 of the IRA added section 1860D–2(b)(8) of the Act to require that, effective for plan years

beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no coinsurance or cost sharing for, an adult vaccine recommended by ACIP that is a covered Part D drug. Further, section 11406 of the IRA added section 1860D–2(b)(9) of the Act to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a one-month supply of each covered insulin product must not exceed the applicable cost-sharing amount for all enrollees. For CYs 2023, 2024, and 2025, this amount was \$35.

Sections 11401(e) and 11406(d) of the IRA directed the Secretary to implement the vaccine and insulin cost sharing changes for CYs 2023, 2024, and 2025 by program instruction or other forms of program guidance. In accordance with the law, we issued several memoranda via the Health Plan Management System (HPMS) that implemented sections 11401 and 11406 of the Act for CYs 2023, 2024, and 2025.⁷ These provisions of the IRA were then codified in the “Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly)” final rule, which appeared in the **Federal Register** on April 15, 2025 (90 FR 15792) (CY 2026 final rule).⁸

In the CY 2026 final rule, consistent with section 1860D–2(b)(9)(B) of the Act, we finalized the requirement that, for CY 2026 and each subsequent year, the applicable cost-sharing amount for a covered insulin product is the lesser of: (1) \$35, (2) an amount equal to 25 percent of the MFP established for the covered insulin product in accordance with Part E of title XI of the Act; or (3) an amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the Part D Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug (MA–PD) plan.

2. Redesigned Part D Benefit (§§ 423.100 and 423.104)

In this rule, we are proposing to codify at §§ 423.100 and 423.104

¹ <https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf>.

² <https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf>.

³ <https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf>.

⁴ <https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf>.

⁵ For more information on the Medicare Drug Price Negotiation Program, please see: <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program>.

⁶ An applicable drug under the Manufacturer Discount Program is a Part D drug approved under a new drug application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA), but does not include a selected drug (as defined in section 1192(c) of the Act) dispensed during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to that drug. Selected drug has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

⁷ See the following HPMS memoranda: Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin (and Revision); Final Contract Year (CY) 2024 Part D Bidding Instructions; and Final CY 2025 Part D Redesign Program Instructions.

⁸ <https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare>.

changes to the Part D benefit made by the IRA related to the deductible, initial coverage limit, the coverage gap, the annual out-of-pocket (OOP) threshold, and alternative prescription drug coverage options.

a. Deductible (§ 423.104(d)(1))

The IRA Part D benefit redesign does not change how the annual deductible for standard prescription drug coverage is calculated. However, as discussed previously, sections 11401 and 11406 of the IRA provide that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to ACIP-recommended adult vaccines or covered insulin products under Part D. We codified these changes in the CY 2026 final rule.⁹ Specifically, the vaccine changes codified at § 423.120(g)(1) and the insulin changes codified at § 423.120(h)(1) state, respectively, that the Part D deductible does not apply with respect to ACIP-recommended adult vaccines and covered insulin products.

In alignment with these changes, we are proposing to revise the regulatory text at § 423.104(d)(1) by adding language to state there, too, that the deductible does not apply to ACIP-recommended adult vaccines or covered insulin products, as defined in § 423.100.

b. Initial Coverage Limit

(§§ 423.104(d)(2) and 423.104(d)(3))

Section 11201 of the IRA amended section 1860D–2(b)(3)(A) of the Act to specify that the initial coverage limit only applies for years preceding CY 2025. Prior to this statutory change, once an enrollee met their deductible, they would enter the initial coverage phase, which would extend until the enrollee's gross covered prescription drug costs, as defined in § 423.100, reached the initial coverage limit. At that point the enrollee would enter the coverage gap phase. The enrollee would remain in the coverage gap phase until the enrollee's incurred costs, as defined in § 423.100, met the OOP threshold, at which point the enrollee would enter the catastrophic phase.

By eliminating the initial coverage limit beginning in CY 2025, the IRA eliminated the coverage gap phase, resulting in a three-phase benefit for Part D prescription drug coverage which includes the deductible phase, the initial coverage phase, and the catastrophic phase. As such, as of CY

2025, there is no longer an initial coverage limit and the initial coverage phase extends to the annual OOP threshold, at which point the catastrophic phase begins. Once an enrollee enters the catastrophic phase, they pay no cost sharing for Part D drugs.

As a result of these changes, we are proposing to revise § 423.104(d)(2) and (d)(3) to reflect the elimination of the initial coverage limit beginning in CY 2025. Specifically, we are proposing to revise the section heading at § 423.104(d)(2) by removing “the initial coverage limit” and replacing it with “prescription drug plans” to accurately reflect the new benefit structure in which there is no initial coverage limit beginning in CY 2025 and to ensure consistency with the statutory changes made by the IRA. This proposed heading language change is intended to accurately encompass the regulations included in the paragraphs that are subordinate to § 423.104(d)(2), which include regulations related to tiered copayments and the specialty tier.

We are also proposing to revise § 423.104(d)(2)(i), which currently specifies that coinsurance for actual costs for covered Part D drugs above the annual deductible applies up to the initial coverage limit. To align our regulations with current statute and the redesigned Part D benefit structure where beneficiaries move directly from the initial coverage phase to the catastrophic phase once they reach the OOP threshold, we propose to revise this language to specify that for each year preceding 2025, this coinsurance applies up to the initial coverage limit and, for 2025 and each subsequent year, this coinsurance applies up to the annual OOP threshold specified in § 423.104(d)(5)(iii).

We also propose to revise § 423.104(d)(3), which specifies how the initial coverage limit is determined. We first propose to correct § 423.104(d)(3) by removing the references to paragraphs (d)(4) and (d)(5) of this section because these paragraphs refer to regulations related to cost sharing in the coverage gap and the out-of-pocket threshold, which do not affect how the initial coverage limit is determined. We propose to revise § 423.104(d)(3)(ii) to specify that the methodology for increasing the initial coverage limit was in effect from 2007 to 2024. We are also proposing to add a new paragraph at § 423.104(d)(3)(iii) to state that, for 2025 and each subsequent year, there is no initial coverage limit.

Finally, we are proposing two conforming changes at § 423.128(e), which refers to the explanation of

benefits that a Part D sponsor must furnish directly to enrollees. First, we propose to revise § 423.128(e)(3)(ii) which states that Part D sponsors are required to include information on the cumulative, year-to-date total amount of benefits provided in relation to the initial coverage limit for the current year in the explanation of benefits provided to enrollees. In alignment with section 1860D–4(a)(4)(B)(i) of the Act, as amended by section 11201 of the IRA, we are proposing to revise § 423.128(e)(3)(ii) by adding language to specify that the requirement to include information about the initial coverage limit was only in effect for years preceding 2025. Second, we propose to revise § 423.128(e)(7) which states that the explanation of benefits must be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including the covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii). In alignment with the elimination of the initial coverage limit and coverage gap phase beginning in CY 2025, we are proposing to add language to specify that the covered Part D spending between the initial coverage limit and the out-of-pocket threshold requirement is only applicable for years preceding 2025.

Rather than striking the regulations that apply through CY 2024, we are proposing to maintain these regulations, with the described revisions, for historical purposes and for any reconciliation activities related to benefit years prior to 2025.

c. Coverage Gap (§§ 423.100 and 423.104(d)(4))

Section 11201 of the IRA eliminated the coverage gap phase of the Part D benefit by amending section 1860D–2(b) of the Act to eliminate the initial coverage limit beginning in CY 2025.

To align with these changes to the Part D benefit, we propose to revise § 423.104(d)(4) by adding language to reflect that the coverage gap phase was eliminated. The proposed revision would state that the methodology for determining cost sharing in the coverage gap that is described in this section applies only for years preceding 2025. This proposed change aligns with our proposed revision to the definition of “coverage gap” in § 423.100 to specify that the coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the OOP threshold during the years 2006 through 2024.

⁹ <https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare>.

We are also proposing to revise § 423.104(d)(4)(iii), which describes the generic gap coinsurance percentage, by adding an end date to paragraph (C) of this section to state that the 25 percent generic gap coinsurance percentage only applied for years 2020 through 2024. This aligns with the IRA's elimination of the coverage gap phase in CY 2025. We also propose to revise § 423.104(d)(4)(iv), which describes the applicable gap coinsurance percentage, by revising paragraph (E) to specify that the applicable gap coinsurance percentage for 2019 was 75 (not 80 percent) and to add an end date indicating that the 75 percent applies for years 2019 through 2024, and removing paragraph (F), which incorrectly stated that the applicable gap coinsurance percentage for 2020 and subsequent years was 75 percent. These changes align with changes made by the Bipartisan Budget Act (BBA) of 2018 and the IRA. Section 53116 of the BBA amended section 1860D–2(b)(2)(D)(ii) of the Act to specify that the applicable gap percentage for 2019 is 75 percent, not 80 percent, thus accelerating by 1 year a reduction in enrollee cost sharing in the coverage gap phase. We note that this revision to paragraph (E) is, in part, a technical correction to align our regulations with the statutory change made by the BBA, which was implemented in 2019. This revision does not change how the applicable gap percentage was calculated in the past, as these amounts were properly determined consistent with the statutory requirement. We additionally propose to add a new paragraph at § 423.104(d)(4)(v) to specify that, for 2025 and each subsequent year, there is no coverage gap.

Finally, we are proposing conforming changes to §§ 422.2267(e)(5)(ii)(B)(1) and 423.2267(e)(5)(ii)(A)(2) which state that information on prescription drug expenses, including information on the deductible, the initial coverage phase, coverage gap, and catastrophic coverage, is required to be included in the Summary of Benefits provided to prospective enrollees. Due to the elimination of the coverage gap in CY 2025, we are proposing to revise §§ 422.2267(e)(5)(ii)(B)(1) and 423.2267(e)(5)(ii)(A)(2) by adding language to specify that the requirement to include information about the coverage gap was only in effect for years preceding 2025.

Even though the coverage gap phase was eliminated in CY 2025, we are proposing to maintain these regulations, with the described revisions, for historical purposes and for any

reconciliation activities related to benefit years prior to 2025.

d. Annual Out-of-Pocket Threshold (§ 423.104(d)(5))

Section 11201 of the IRA amended section 1860D–2(b)(4)(B)(i) of the Act to limit the annual OOP threshold for CY 2025 and each subsequent year. As amended, section 1860D–2(b)(4)(B)(i)(VII) of the Act specifies that the annual OOP threshold is \$2,000 for CY 2025. For subsequent years, section 1860D–2(b)(4)(B)(i)(VIII) of the Act specifies that the annual OOP threshold will be increased by the annual percentage increase described in section 1860D–2(b)(6). Accordingly, as specified in the CY 2026 Rate Announcement, the annual OOP threshold for CY 2026 was determined to be \$2,100.¹⁰ This amount was calculated, consistent with section 1860D–2(b)(4)(B) of the Act, by multiplying the CY 2025 OOP threshold amount of \$2,000 by the 2026 annual percentage increase and rounding to the nearest multiple of \$50. Once an enrollee's incurred costs, as defined at § 423.100, exceed the annual OOP threshold, an enrollee will enter the catastrophic phase where there is no cost sharing for Part D drugs.

As a result of these changes, we are proposing to revise § 423.104(d)(5) to state the specific years for which certain aspects of this section apply and describe the new methodology for determining the annual OOP threshold, consistent with section 1860D–2(b)(4)(B)(i) of the Act.

We are proposing to revise § 423.104(d)(5)(i) to specify that, once an enrollee's incurred costs, as defined at § 423.100, exceed the annual OOP threshold described in paragraph (d)(5)(iii) of this section, they would have \$0 cost sharing for 2024 and each subsequent year and, for each year preceding 2024, the cost-sharing structure currently outlined at paragraphs (d)(5)(i)(A) and (d)(5)(i)(B) of this section would apply. We also propose to revise § 423.104(d)(5)(i)(A)(2) to specify that the methodology described in this section for determining an enrollee's copayment amount applies through 2023. These proposed changes reflect the elimination of enrollee cost sharing for Part D drugs in the catastrophic phase beginning in CY 2024, consistent with section 1860D–2(b)(4)(A)(i) of the Act, as amended by section 11201 of the IRA.

We propose to revise § 423.104(d)(5)(iii)(F) to add an end date to state that this paragraph describes

how the annual OOP threshold was determined for years 2021 through 2024. We also propose to add new § 423.104(d)(5)(iii)(G) to establish that for 2025, the annual OOP threshold was set at \$2,000, consistent with section 1860D–2(b)(4)(B)(i)(VII) of the Act. Additionally, we are proposing to add new § 423.104(d)(5)(iii)(H) to specify the methodology for determining the annual OOP threshold for 2026 and each subsequent year. Consistent with section 1860D–2(b)(4)(B)(i)(VIII) of the Act, we propose that the annual OOP threshold for 2026 and each subsequent year would be the amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest \$50.

e. Alternative Prescription Drug Coverage (§ 423.104(e)(5)) and Enhanced Alternative Coverage (§ 423.104(f)(1))

Part D sponsors must provide their enrollees with qualified prescription drug coverage which, as defined at § 423.100, means coverage that consists of either: (1) standard prescription drug coverage or (2) alternative prescription drug coverage. Standard prescription drug coverage, as defined at § 423.100, means coverage of Part D drugs that meets the requirements of § 423.104(d) and includes two distinct types of coverage: (1) defined standard coverage and (2) actuarially equivalent (AE) standard coverage.

Prior to the implementation of the IRA, defined standard coverage consisted of coverage of covered Part D drugs subject to an annual deductible, 25 percent coinsurance for costs above the annual deductible but at or below an initial coverage limit, coinsurance that was equal to the costs of non-applicable and applicable drugs during the coverage gap multiplied by the gap coinsurance percentages, and catastrophic coverage with nominal cost sharing for the remainder of the coverage year once an enrollee's incurred costs, as defined in § 423.100, exceeded the annual OOP threshold. After the implementation of the IRA, defined standard coverage, as discussed in more detail in the introduction of this section of the proposed rule, now consists of an annual deductible, an initial coverage phase where the enrollee pays 25 percent coinsurance for covered Part D drugs until they reach the annual OOP threshold (\$2,100 for CY 2026), and the catastrophic phase where the enrollee pays no cost sharing for Part D drugs. AE standard coverage, as defined at § 423.100, provides for cost sharing as described in

¹⁰ <https://www.cms.gov/files/document/2026-announcement.pdf>.

§ 423.104(d)(2)(i)(B) or cost sharing as described in § 423.104(d)(5)(ii), or both. In other words, under an AE plan, Part D sponsors modify certain benefit parameters, such as cost-sharing structures, while maintaining the same actuarial value. The changes the IRA made to the defined standard benefit are discussed in detail in the preceding sections of this proposed rule.

The IRA also, through section 11201 which amended section 1860D–2(c) of the Act, made changes to the requirements for alternative prescription drug coverage. Alternative prescription drug coverage, as defined in § 423.100, means coverage of Part D drugs, other than standard prescription drug coverage, that meets the requirements of § 423.104(e). Alternative prescription drug coverage includes two types of coverage: (1) basic alternative coverage and (2) enhanced alternative coverage. Both basic alternative and enhanced alternative coverage must provide access to negotiated prices, coverage of Part D drugs, and meet the requirements described in § 423.104(e).

Basic alternative coverage is alternative coverage that is actuarially equivalent to defined standard coverage, as determined through the processes and methods established under § 423.265(d)(2). Prior to the implementation of the IRA, Part D sponsors offering basic alternative coverage could, within the parameters for alternative prescription drug coverage as described in § 423.104(e), combine certain features to maintain an actuarial value of coverage equal to defined standard prescription drug coverage, such as: (1) reducing the deductible, (2) making changes in cost sharing in an actuarially equivalent manner to the 25 percent cost sharing above the deductible and below the initial coverage limit under defined standard coverage and in an actuarially equivalent manner to the gap coverage coinsurance during the coverage gap, or (3) modifying the initial coverage limit. With the changes made to the Part D benefit by the IRA, including the elimination of the initial coverage limit and the coverage gap, certain features that could be offered by basic alternative plans are no longer available. Thus, we are proposing to revise our regulations at § 423.104(e) to align with these changes, as discussed in more detail later.

Enhanced alternative coverage is alternative coverage that includes both required basic prescription drug coverage and supplemental benefits, as described at § 423.104(f)(1)(ii). Prior to the implementation of the Part D benefit redesign provisions in the IRA,

supplemental benefits included: the coverage of drugs that are specifically excluded from the definition of a Part D drug in § 423.100 under paragraph (2)(ii) and/or any one or more of the following changes that increase the actuarial value of benefits above the actuarial value of defined standard prescription drug coverage:

- Reduction (or elimination) of the defined standard deductible.
- Reduction of cost sharing in the initial coverage phase.
- Increase of the initial coverage limit threshold.
- Additional cost-sharing reduction in the coverage gap phase.
- Reduction (or elimination) of cost sharing in the catastrophic phase.

As noted in the Final CY 2025 Part D Redesign Program Instructions, section 1860D–2(a)(2)(A)(i) of the Act does not include a reduction in the annual OOP threshold in its list of permissible supplemental benefits, and we have never interpreted such provision to allow for a reduction in the annual OOP threshold. Because the IRA established a defined annual OOP threshold of \$2,000 for CY 2025, and an amount equal to the previous year's OOP threshold increased by the annual percentage increase for 2026 and subsequent years, and did not modify the list of permissible supplemental benefits in section 1860D–2(a)(2)(A)(i) of the Act to include a reduction in the annual OOP threshold, Part D sponsors may not lower the annual OOP threshold below the specified amount. Additionally, the IRA eliminated cost sharing in the catastrophic phase beginning in CY 2024 and eliminated the coverage gap phase and replaced the Coverage Gap Discount Program with the Manufacturer Discount Program beginning in CY 2025. Thus, only the following supplemental benefits remain as possible enhancement features: coverage of drugs that are specifically excluded from the definition of a Part D drug, and/or:

- Reduction (or elimination) of the defined standard deductible.
- Reduction of cost sharing in the initial coverage phase.

Given these changes to alternative prescription drug coverage, we propose to revise § 423.104(e)(5) to align our requirements for alternative prescription drug coverage with the changes made by the IRA. We are also proposing to revise § 423.104(f)(1) to align our requirements for enhanced alternative drug coverage with the changes made by the IRA.

We first propose to revise § 423.104(e)(5) to establish a distinction between the requirements for alternative prescription drug coverage that are

applicable for years preceding 2025 and requirements for 2025 and each subsequent year. Specifically, we are proposing to add language that, for years preceding 2025, alternative prescription drug coverage is required to provide coverage that is designed to provide payment for costs incurred for covered Part D drugs that is equal to the initial coverage limit. We also propose to add language stating that, for 2025 and each subsequent year, this coverage must be equal to the annual OOP threshold, consistent with section 1860D–2(c)(1)(C) of the Act. Similarly, we propose to revise § 423.104(e)(5)(i) to specify that when calculating the required payment amount for costs incurred for covered Part D drugs, the amount the initial coverage limit exceeds the deductible should be used for years preceding 2025, and the amount the annual OOP threshold exceeds the deductible should be used for 2025 and each subsequent year. We propose maintaining § 423.104(e)(5)(ii) without change; therefore, the amount calculated in § 423.104(e)(5)(i) would be multiplied by 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section to determine the required payment amount.

Finally, we propose to revise § 423.104(f)(1) to specify that an increase in the initial coverage limit could be considered a supplemental benefit only for years preceding 2025. This change reflects the elimination of the initial coverage limit beginning in CY 2025. All other requirements for enhanced alternative coverage that are described in § 423.104(f) remain applicable under the redesigned Part D benefit. Therefore, we are not proposing any additional changes to this section.

3. Specialty Tier (§ 423.104)

Section 1860D–2(b)(2) of the Act established the parameters of the Part D program's defined standard benefit and allows for alternative benefit designs that are actuarially equivalent to the defined standard benefit, including the use of tiered formularies. Although not required, Part D sponsors are permitted to include a specialty tier in their plan design. A specialty tier, as defined in § 423.104(d)(2)(iv), is a formulary cost-sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(2) of this section) that are greater than the specialty-tier cost threshold specified in paragraph (d)(2)(iv)(A) of this section. Consistent with § 423.104(d)(2)(iv)(D), Part D sponsors may maintain up to two specialty tiers.

Use of one or two specialty tiers provides the opportunity for Part D sponsors to manage high-cost drugs apart from tiers that have less expensive drugs. Our policies for the specialty tier aim to strike the appropriate balance between plan flexibility and Part D enrollee access to drugs, consistent with our statutory authority.

In the final rule titled “Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” (CY 2022 final rule) which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864),¹¹ We codified several important aspects of the specialty-tier policy that had previously been maintained through subregulatory guidance, including our methodology for setting and increasing the specialty-tier cost threshold and determining the maximum allowable cost sharing for specialty-tier drugs.

In the CY 2022 final rule, we codified our methodology for setting the specialty-tier cost threshold at § 423.104(d)(2)(iv)(A), as well as our methodology for increasing this cost threshold at § 423.104(d)(2)(iv)(B). These rules describe our processes for setting a minimum dollar-per-month threshold amount to determine which drugs are eligible, based on relative high cost, for inclusion on the specialty tier as well as adjusting this threshold to maintain approximately one percent of Part D drugs as specialty-tier eligible. In the CY 2022 final rule, we also codified, at § 423.104(d)(2)(iv)(D)(1) through (3), the maximum allowable cost sharing for drugs on the specialty tier between 25 and 33 percent coinsurance. By codifying this rule, we aimed to prevent discriminatory formulary structures and protect Part D enrollees with certain disease states that are treated only by specialty-tier eligible drugs. This “25/33 percent” maximum allowable cost sharing means that we approve cost sharing for the specialty tier of no more than 25 percent coinsurance after the standard deductible and before the initial coverage limit (ICL), or up to 33 percent coinsurance for plans with decreased or no deductible under alternative prescription drug coverage designs and before the ICL.

The implementation of the IRA has made it necessary for us to make

changes to our current specialty-tier regulations related to adjusting the specialty-tier cost threshold and determining the maximum allowable cost sharing to align with the redesigned Part D benefit. In this rule, we propose to codify technical and conforming changes to our specialty-tier regulations at § 423.104.

a. Technical Correction to the Specialty-Tier Cost Threshold Determination (§ 423.104(d)(2)(iv)(A)(4))

We are proposing a technical correction in § 423.104(d)(2)(iv)(A)(4), which describes how the specialty-tier cost threshold is determined for the plan year. The current regulation text incorrectly refers to paragraph (d)(2)(iii) for the cost threshold determination, but it should refer to the top one percent methodology for determining the specialty-tier cost threshold at paragraph (d)(2)(iv)(A)(3). We therefore propose to correct this inadvertent technical error in this proposed rule.

b. Limit on Specialty-Tier Cost Threshold Adjustment (§ 423.104(d)(2)(iv)(B))

We annually calculate a minimum dollar-per-month threshold amount to determine which drugs are eligible, based on relative high cost, for inclusion on the specialty tier. This cost threshold is adjusted to maintain approximately 1 percent of Part D drugs as specialty-tier eligible. In the CY 2022 final rule, we codified at § 423.104(d)(2)(iv)(B) our methodology to increase the specialty-tier cost threshold as follows:

(1) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(3) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(2) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(3) of this section to the nearest \$10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

Our current regulation only contemplates increasing the specialty-tier cost threshold and does not consider decreasing the threshold when market conditions might warrant such a change. Given the many changes made to the Part D benefit by the IRA, we believe that it may be necessary in future years to decrease the specialty-tier cost threshold due to reductions in Part D drug costs. In general, shifting market dynamics, such as increased utilization of lower cost generic drugs,

could potentially lead to reductions in Part D drug costs. The Medicare Drug Price Negotiation Program, as established in Part E of title XI of the Act, which permits the Secretary to negotiate MFPs for certain high expenditure, single source drugs and biological products with participating manufacturers, could also lead to a future need for a downward adjustment. The MFPs for the first 10 selected drugs are scheduled to go into effect on January 1, 2026, with new MFPs taking effect and new drugs being selected for negotiation each subsequent year. Therefore, it is possible that as a result of general market dynamics and more high expenditure drugs being selected for negotiation and their negotiated MFPs taking effect, the methodology for determining the specialty-tier cost threshold, as described in § 423.104(d)(2)(iv)(A), may yield an amount that is at least 10 percent below the previous plan year’s specialty-tier cost threshold.

Thus, we propose to revise § 423.104(d)(2)(iv)(B)(1) and (2) by adding language to allow us to reduce the cost threshold under certain circumstances. Specifically, in paragraph (B)(1) of this section, we are proposing to replace “increase” with “modifies” and add “or below” following “10 percent above.” In paragraph (B)(2), we are proposing to replace “increase” with “modification.”

c. Specialty Tier Maximum Allowable Cost Sharing (§ 423.104(d)(2)(iv)(D))

Each year, we set the maximum allowable cost sharing for the specialty tier based on the plan’s deductible, in accordance with § 423.104(d)(2)(iv)(D). The intent of this policy is to ensure a plan’s value is reflective of the defined standard benefit. The regulation limits a plan with the full defined standard deductible to a 25 percent coinsurance on its specialty tier but allows a plan that fully eliminates the deductible up to a 33 percent coinsurance on its specialty tier. Based on the pre-IRA benefit design, we determined that the 33 percent maximum coinsurance was mathematically equivalent to the effective coinsurance for a beneficiary who would have paid the defined standard deductible for any given year plus the 25 percent coinsurance in the initial coverage phase until their drug costs reached the initial coverage limit. In other words, prior to CY 2025, beneficiary OOP costs divided by total drug costs equaled a 33 percent effective

¹¹ <https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare>.

coinsurance for the beneficiary

regardless of the plan deductible,
represented by the following equation:

$$\frac{(\text{Beneficiary OOP costs})}{(\text{Total drug costs})} = \text{Effective coinsurance}$$

To operationalize the concept of maximum allowable cost sharing for the specialty tier based on the plan's deductible, CMS, in the CY 2022 final

rule, codified the following calculation at § 423.104(d)(2)(iv)(D)(3) to determine the deductible range that corresponded to each specialty-tier coinsurance

percentage point from 25 percent through 33 percent. Thus, under the pre-IRA Part D benefit design, we used this equation for the calculation:

$$\frac{\text{Deductible} + \text{Coinsurance (ICL - Deductible)}}{\text{ICL}} = 33\%$$

Consistent with the first equation, the numerator here represents beneficiary OOP costs while the denominator represents total drug costs, resulting in an effective coinsurance of 33 percent, to align with the defined standard benefit. This equation was then solved for the deductible, and each specialty-tier coinsurance percentage point was inserted, to calculate the maximum allowable deductible value corresponding to that coinsurance percentage.

However, in CY 2025, the ICL was eliminated and, as a result, the methodology codified at § 423.104(d)(2)(iv)(D)(3) was no longer valid. Therefore, in the Final CY 2025 Part D Redesign Program Instructions,¹² we established a new methodology to determine the specialty-tier coinsurance/deductible ranges to represent the effective coinsurance for a beneficiary under the redesigned Part D benefit. In the Final CY 2026 Part D Redesign Program Instructions,¹³ we continued to use the methodology

outlined in the Final CY 2025 Part D Redesign Program Instructions.

In accordance with the Final CY 2025 Part D Redesign Program Instructions, we are now proposing to codify this methodology for determining the specialty-tier coinsurance/deductible ranges to represent the effective coinsurance for a beneficiary under the Part D benefit. To ensure that a plan's value is reflective of the defined standard benefit, we are proposing to codify a methodology similar to the methodology used to calculate the cost-sharing requirements in § 423.104(d)(2)(iv)(D). For Part D plans with the full deductible provided under the defined standard benefit, the coinsurance is 25 percent, consistent with the defined standard benefit. Using the CY 2025 defined standard benefit parameters of a \$590 deductible, a \$2,000 annual OOP threshold, and a 25 percent coinsurance after the deductible is met and before the annual OOP threshold is reached, the total drug costs can be calculated at \$6,230. This results in an effective coinsurance of 32.1

percent. To ensure that coinsurance for the specialty tier remains in alignment with cost sharing under the defined standard benefit, we are retaining the 33 percent maximum coinsurance currently effective at § 423.104(d)(2)(iv)(D)(2).

We are proposing to use, as in previous years, an effective coinsurance equation to calculate the deductible that corresponds to each specialty-tier coinsurance percentage point from 25 percent through 33 percent. Consistent with our decision to retain the 33 percent maximum coinsurance, we are also proposing to use 33 percent to calculate the deductible that corresponds to each specialty-tier coinsurance percentage point. This equation would continue to represent beneficiary OOP costs in the numerator divided by total drug costs in the denominator. The following equation illustrates how we would calculate the effective coinsurance for the Part D benefit for purposes of calculating specialty-tier cost-sharing percentages:

$$\frac{(\text{OOP Threshold})}{\left(\frac{(\text{OOP Threshold} - \text{Deductible})}{(\text{Maximum allowable specialty tier coinsurance})} + \text{Deductible} \right)} = 33\%$$

As with the previous methodology, the equation is solved for the deductible, and each maximum allowable specialty tier coinsurance

value is inserted, to determine the maximum allowable deductible value corresponding to that coinsurance. For

example, the results for CY 2026 are shown in Table 1.

¹² <https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf>.

¹³ <https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf>.

TABLE 1: CY 2026 SPECIALTY-TIER COINSURANCE THRESHOLDS

Deductible Range	Maximum Allowable Specialty-Tier Coinsurance
\$601.98 to \$615.00	25%
\$523.05 to \$601.97	26%
\$441.93 to \$523.04	27%
\$358.52 to \$441.92	28%
\$272.74 to \$358.51	29%
\$184.46 to \$272.73	30%
\$93.59 to \$184.45	31%
\$0.01 to \$93.58	32%
\$0	33%

Consistent with the approach taken for both CY 2025 and CY 2026 as detailed in the Final CY 2025 Part D Redesign Program Instructions, we are proposing to codify this methodology for determining specialty-tier coinsurance/deductible ranges. Thus, we propose to revise § 423.104(d)(2)(iv)(D)(3)(i) to describe how the maximum coinsurance percentage was determined for years preceding 2025. We also propose to add new § 423.104 (d)(2)(iv)(D)(3)(ii) to describe the methodology for calculating the maximum coinsurance percentage for 2025 and each subsequent year.

4. Changes in True Out-of-Pocket (TrOOP) Costs (§§ 423.100 and 423.464)

A beneficiary’s progression through the Part D benefit phases is determined by the total amount of costs incurred by the beneficiary for covered Part D drugs in the plan year. This amount is also referred to as the beneficiary’s accumulated TrOOP spending. Incurred costs are defined at section 1860D–2(b)(4)(C) of the Act and the statutory definition has been revised several times since the beginning of the Part D program. Between 2005 and 2010, TrOOP expenditures represented costs actually paid by the beneficiary, another person on behalf of the beneficiary, or a qualified State Pharmaceutical Assistance Program (SPAP). The Act also expressly excluded certain costs from the definition of TrOOP, including costs “reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement.”

In January 2005, we published the final rule titled, “Medicare Program; Medicare Prescription Drug Benefit” (70 FR 4194), in which we initially codified the rules applicable to incurred costs at § 423.100 (hereinafter referred to as the January 2005 Medicare Final Rule). In that rule, we established that the terms

“insurance or otherwise” are separate terms with separate definitions. The term “insurance” refers to a health plan that provides or pays the cost of covered Part D drugs, including, but not limited to health insurance coverage, an MA plan, and a PACE organization. The term “or otherwise” refers to government-funded health programs, and accordingly, we defined the term “government-funded health programs” to mean any program established, maintained, or funded—in whole or in part—by the Federal government, the governments of States or political subdivisions of States, or any agency or instrumentality of these governments which uses public funds in whole or in part to provide to, or pay on behalf of, an individual the cost of Part D drugs at § 423.100.

Enacted into law on March 23, 2010, section 3314 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) added section 1860D–2(b)(4)(C)(iii) of the Act to specify that costs borne or paid for by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization, and costs borne or paid for by an AIDS Drug Assistance Program (ADAP) count as incurred costs and accumulate towards TrOOP. In the final rule titled, “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes,” which appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we revised the definition of incurred cost at § 423.100 to reflect the amendments to section 1860D–2(b)(4)(C)(iii) of the Act made by the PPACA. Specifically, we revised the regulation to include payments by the IHS, an Indian tribe or tribal organization, or an urban Indian organization (referred to as I/T/U pharmacy in § 423.100) or under an ADAP in the definition of incurred costs

at § 423.100. We also amended § 423.464(f)(2) to state that expenditures made by IHS, an Indian tribe or tribal organization, or an urban Indian organization or under an ADAP are not required to be excluded when determining whether a Part D enrollee has satisfied the out-of-pocket threshold.

Section 11201 of the IRA further amended section 1860D–2(b)(4)(C) of the Act to update the definition of incurred costs. Section 1860D–2(b)(4)(C)(iii)(II) of the Act, as added by the IRA, amended the definition of incurred costs to include, for CY 2025 and subsequent years, costs incurred that are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program. In addition, the IRA provided that, for beneficiaries who have opted into the Medicare Prescription Payment Plan described in section 1860D–2(b)(2)(E) of the Act, election into such program will not impact how a beneficiary moves through the Part D benefit or what counts towards TrOOP. Under section 1860D–2(b)(4)(F) of the Act, a Medicare Prescription Payment Plan participant’s TrOOP-eligible costs that are paid by their Part D plan under the Medicare Prescription Payment Plan shall be treated as incurred costs.

Section 11201(f) of the IRA directed the Secretary to implement section 11201 of the IRA for 2024, 2025, and 2026 by program instruction or other forms of program guidance. In the Final CY 2025 Part D Redesign Program Instructions, we released guidance to implement the IRA’s additions to section 1860D–2(b)(4)(C) of the Act. Specifically, we stated that

supplemental Part D coverage provided by enhanced alternative Part D plans and other health insurance (OHI) will be counted as incurred costs and included in the calculation of TrOOP for CY 2025. This includes supplemental coverage provided by Employer Group Waiver Plans (EGWPs), plan reductions in cost sharing for enrolled beneficiaries, such as reductions by Medicare-Medicaid Plans and D-Special Needs Plans (SNPs), and Center for Medicare and Medicaid Innovation (CMMI) model benefits that reimburse costs for covered Part D drugs (unless stated otherwise in an applicable CMMI model's respective Request for Applications or model guidance). In response to comments received, we explained that including supplemental coverage provided by enhanced alternative Part D plans in addition to OHI is required by the plain language of the statute. Specifically, by excluding "coverage provided by a prescription drug plan or an MA-PD plan that is basic prescription drug coverage" from the definition of costs "reimbursed through insurance," the text of section 1860D-2(b)(4)(C)(iii)(II) indicates that drug coverage provided by Part D plans other than basic prescription drug coverage is included in the definition of costs "reimbursed through insurance." This would include enhanced alternative supplemental benefits. If the provision only included EGWP supplemental coverage in the definition of costs "reimbursed through insurance," then the statute would have explicitly included EGWP supplemental coverage in the definition of "costs reimbursed through insurance" and expanded the exclusion clause to apply to both basic prescription drug coverage and enhanced alternative supplemental coverage.

We further stated in the Final CY 2025 Part D Redesign Program Instructions that under section 1860D-2(b)(4)(C)(iii)(II) of the Act, only amounts reimbursed by supplemental coverage will be newly included in the calculation of TrOOP. For enhanced alternative plans, plan liability is mapped to the defined standard benefit to distinguish between basic and supplemental benefits provided under the Part D sponsor. Because of this, if beneficiary cost sharing is greater than what it would have been under the defined standard benefit, a negative value is recorded on a Prescription Drug Event (PDE) record for the field representing the value of the supplemental coverage. Such negative values will be disregarded (that is, be treated as zero) when calculating

TrOOP, because they do not represent reimbursement to the beneficiary. In response to comments received, we explained that, while excluding such negative values from TrOOP can overstate the net value of total supplemental benefits provided to beneficiaries over the course of the year, including negative values in TrOOP would inappropriately disregard any beneficiary cost sharing in excess of the defined standard cost sharing amount when calculating TrOOP. This would particularly disadvantage certain beneficiaries who have patterns of utilization that disproportionately include this situation. For example, if a beneficiary in an enhanced alternative plan has higher cost sharing than the defined standard benefit for a maintenance medication, including the negative values in TrOOP could significantly disadvantage that beneficiary as these negative values would continually offset part of the payments the beneficiary actually paid OOP. This would create some circumstances where certain beneficiaries have a net negative value for their supplemental benefits when they reach the \$2,100 OOP threshold, which means they would have to pay more than \$2,100 OOP to reach the catastrophic phase for CY 2026.

Additionally, we noted that section 1860D-2(b)(4)(C)(iii)(II) of the Act states that reimbursements through "certain other third party payment arrangements" are to be included in the calculation of TrOOP. We did not identify any third party payment arrangements in addition to those described in the preceding paragraphs that could be included in the calculation of TrOOP. For instance, primary payer amounts paid on Medicare as secondary payer (MSP) claims are a category of third party payments that we considered for TrOOP eligibility. We determined that these payments should remain excluded from TrOOP due to the requirements at section 1862(b) of the Act, which was not amended by the IRA. As such, for 2025, we did not count as incurred costs any other third party payments not considered TrOOP-eligible prior to 2025. In the Final CY 2025 Part D Redesign Program Instructions, we also solicited comment on whether interested parties are aware of other third party payments that could be included under section 1860D-2(b)(4)(C)(iii)(II) of the Act. No commenters identified additional third party payments that they believed should be included in TrOOP. We also did not receive any comments on the

Final CY 2026 Part D Redesign Program Instructions recommending that we include any other third party payments towards TrOOP.

Further, we stated that, as required by section 1860D-2(b)(4)(C)(iii)(II) of the Act, any manufacturer payments made under the Manufacturer Discount Program, which was newly created under the IRA, do not count as incurred costs and are not included in the calculation of TrOOP in 2025.

Finally, we stated that for beneficiaries who have opted into the Medicare Prescription Payment Plan described in section 1860D-2(b)(2)(E) of the Act, as added by section 11202 of the IRA, election into such program will not impact how a beneficiary moves through the Part D benefit or what counts towards TrOOP. Under section 1860D-2(b)(4)(F) of the Act, as codified at § 423.137(c)(4), a Medicare Prescription Payment Plan participant's TrOOP-eligible costs that are paid by their Part D plan under the Medicare Prescription Payment Plan shall be treated as incurred costs.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the policy with respect to incurred costs, also applied in CY 2026.

In this proposed rule, we propose to codify at § 423.100 the policies we established in the Final CY 2025 Part D Redesign Program Instructions for CY 2025 and applied via the Final CY 2026 Part D Redesign Program Instructions for CY 2026 with respect to the definition of incurred costs for 2025 and subsequent years, without modification. These policies are currently in effect for CY 2026. Specifically, we propose to add a new subparagraph (3) to the definition of incurred costs at § 423.100 defining incurred costs for 2025 and subsequent years to include costs that are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a PDP or an MA-PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program under section 1860D-14C of the Act. We also propose to amend § 423.464(f)(2)(i)(C) to remove the exclusion of expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage and replace it with an exclusion limited to expenditures for covered Part D drugs made by

government-funded health programs or the coverage provided by a PDP or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program.

5. Policy for Drugs Not Subject to Defined Standard Deductible (§ 423.104)

Under sections 1860D–2(b) and (c) of the Act, as amended by section 11201 of the IRA, the coverage gap phase was eliminated in CY 2025. Beginning in CY 2025, a beneficiary leaves the initial coverage phase and enters the catastrophic phase once they incur enough TrOOP-eligible costs to meet the annual OOP threshold. Accordingly, under section 1860D–14A(h) of the Act, as added by section 11201 of the IRA, the Coverage Gap Discount Program sunset effective January 1, 2025. Section 11201 of the IRA added section 1860D–14C of the Act, which created the Manufacturer Discount Program beginning January 1, 2025. Under section 1860D–14C(b)(1)(A) of the Act, manufacturers that enter into a Manufacturer Discount Program agreement will provide discounts on applicable drugs, typically amounting to 10 percent of the negotiated price for enrollees in the initial coverage phase and 20 percent of the negotiated price for enrollees in the catastrophic phase, in CY 2025 and subsequent years.

Manufacturer discounts are available under the Manufacturer Discount Program once a beneficiary becomes an “applicable beneficiary.” Section 1860D–14C(g)(1) of the Act defines an applicable beneficiary as an individual who, on the date of dispensing a covered Part D drug, is enrolled in a PDP or MA–PD plan, is not enrolled in a qualified retiree prescription drug plan, and has incurred TrOOP-eligible costs that exceed the defined standard deductible specified in section 1860D–2(b)(1) of the Act. TrOOP-eligible costs for drugs not subject to the defined standard deductible, specifically covered insulin products, as well as TrOOP-eligible costs for drugs not subject to a non-defined standard plan deductible or drugs subject to a reduced deductible under non-defined standard plans, all count towards a beneficiary’s satisfaction of the defined standard deductible.

In the Final CY 2025 Part D Redesign Program Instructions, we established a policy for drugs not subject to the defined standard deductible to address situations where a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible. The policy also addresses

situations where a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the defined standard deductible amount. The component of the definition of an applicable beneficiary at section 1860D–14C(g)(1)(C) of the Act creates the possibility for a beneficiary to encounter these situations; therefore, this policy was necessary to ensure that such situations are treated similarly by all Part D plan sponsors.

We established that in CY 2025, if a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible, they will be both an applicable beneficiary under the Manufacturer Discount Program, as we propose to define at § 423.100, and be deemed to have satisfied their plan deductible.

Furthermore, we established that, if a plan offers a non-defined standard plan deductible—whether that be a lower deductible than the defined standard deductible or a deductible that applies for a subset of covered Part D drugs—and a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the defined standard deductible amount, discounts under the Manufacturer Discount Program are not available. As such, the plan is responsible for covering the portion of costs that would be covered by the manufacturer discount if the beneficiary were an applicable beneficiary until the beneficiary’s TrOOP exceeds the defined standard deductible and they become an applicable beneficiary. The same guidance applies when a beneficiary under any Part D plan is dispensed a covered insulin product or ACIP-recommended vaccine before they have incurred TrOOP-eligible costs at or above the defined standard deductible amount.

For example, an enhanced alternative plan has a tiered formulary, does not charge a deductible for tier 1 drugs, and charges 20 percent coinsurance for drugs in that tier. A beneficiary’s first fill of the year is for a \$200 tier 1 drug, meaning they pay \$40 out of pocket. The beneficiary has not incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible of \$615 (and has \$415 in remaining TrOOP-eligible costs before they satisfy the deductible) and does not meet the definition of an applicable beneficiary under the Manufacturer Discount Program. Therefore, the plan must cover the 10 percent of costs that would be

covered by the manufacturer discount if the beneficiary were an applicable beneficiary.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the policy with respect to drugs not subject to the defined standard deductible, also applied in CY 2026. We also established that the policy for drugs not subject to the defined standard deductible also applies to selected drugs for CY 2026. Specifically, we stated that if a plan offers a non-defined standard plan deductible—whether that be a lower deductible than the defined standard deductible or a deductible that applies for a subset of covered Part D drugs—and a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the defined standard deductible amount, the selected drug subsidy is not available for selected drugs during a price applicability period. As such, for a selected drug during a price applicability period, the plan is responsible for covering the portion of costs that would be covered by the selected drug subsidy if the beneficiary were an applicable beneficiary until the beneficiary’s TrOOP exceeds the defined standard deductible and they become an applicable beneficiary.

In this proposed rule, we propose to codify the policy for drugs not subject to the defined standard deductible that are in effect for 2025 and 2026 without modification. Specifically, we propose to codify the policy for drugs not subject to defined standard deductible at a new § 423.104(j).

6. Annual Indexing of Part D Benefit Parameters Using the Annual Percentage Increase in Drug Expenditures (API) and Consumer Price Index (CPI) (§§ 423.104, 423.782)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA) added sections 1860D–2(b) and 1860D–14(a) of the Act directing the Secretary to index certain Part D benefit parameters each year, which include, but are not limited to, the deductible limit and low-income cost-sharing amounts. The required annual adjustments ensure that the actuarial value of the drug benefit remains consistent with changes in Part D drug expenditures and general inflation. The MMA established two indices for adjusting Part D benefit parameters: (1) the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in

the U.S. for Part D eligible individuals under section 1860D–2(b)(6) of the Act (referred to as the API); and (2) the annual percentage increase in the Consumer Price Index based on all items per a U.S. city average under section 1860D–14(a)(4)(A) of the Act (referred to as the CPI).

In the January 2005 Medicare Final Rule (70 FR 4194), establishing the regulatory framework for the Medicare Part D prescription drug benefit program created by the MMA. This rule codified the statutory requirements for annual adjustments of the deductible under section 1860D–2(b)(6) of the Act and low-income cost-sharing amounts under section 1860D–14(a) of the Act, using the API and the CPI. The rule also established the regulatory basis for annual adjustments to additional Part D parameters, including the annual out-of-pocket threshold and retiree drug subsidy (RDS) cost thresholds, to maintain the actuarial integrity of the benefit structure as drug costs and economic conditions change over time.

In accordance with the statute and corresponding regulation, the following Part D standard benefit, low-income subsidy, and RDS program parameters are updated using the API:

- *Standard Benefit Deductible*—section 1860D–2(b)(1)(A)(ii) of the Act; § 423.104(d)(1)(ii).
- *Initial Coverage Limit*—section 1860D–2(b)(3)(A)(ii) of the Act; § 423.104(d)(3)(ii).
- *OOP Threshold*—section 1860D–2(b)(4)(B)(i)(VIII) of the Act.
- *Maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees* (income less than 150 percent, but greater than 100 percent of Federal Poverty Level (FPL), not including institutionalized individuals)—section 1860D–14(a)(1)(D)(iii) of the Act; § 423.782(a)(2)(i).
- *RDS Cost threshold*—section 1860D–22(a)(3)(B)(i)(I) of the Act; § 423.886(b)(3).
- *RDS Cost limit*—section 1860D–22(a)(3)(B)(i)(II) of the Act; § 423.886(b)(3).

The CPI is used to update the following Part D low-income subsidy and cost-sharing program benefit parameter:

- *Maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees* (income less than 100 percent of the FPL)—section 1860D–14(a)(1)(D)(ii) of the Act; § 423.782(a)(2)(iii)(A).

While sections 1860D–2(b)(6) and 1860D–14(a)(4)(A) describe the parameter adjustments as an “increase” when referring to API and CPI, we have historically applied them multidirectionally, including decreasing the parameter values in the event of a decrease in annual Part D expenditures or deflation, to ensure that the actuarial value of the drug benefit remains consistent each year.

The current regulations do not describe the specific methods used to calculate the annual percentage increases. Instead, the specific methods for calculating the annual percentage increases in drug expenditures and CPI that are applied to the Part D benefit parameters have been proposed for each CY in the Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Advance Notice) and finalized in the Announcement of Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Rate Announcement). In this proposed rule, we propose to codify these methodologies in regulation. We also propose making certain technical changes to current regulations related to indexing certain benefit parameters for low-income individuals. Although we are proposing to codify the calculation methodology for the API and CPI in this rule, we will continue to publish the annual percentage increases in drug expenditures and CPI and updated Part D benefit parameters for each CY through the Advance Notice and Rate Announcement. The projections and calculations used in the methodologies described at proposed §§ 423.104 and 423.782 are made using generally accepted actuarial principles and practices. In applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including taking into account information such as changes in legislation (such as changes in Medicare benefits), Medicare payment policy, trends over several

years of data, and external variables (such as public health emergencies); selecting among different approaches (such as weighting for utilization and using average or median values); and in selecting data or data samples.

Calculation of the Annual Percentage Increase in Drug Expenditures

Section 1860D–2(b)(6) of the Act defines the API for each year as the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals, for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify. We calculate the aggregate expenditures for Part D drugs using the GCPDC instead of an alternative cost measure such as actual net drug costs, because gross drug costs reflect the prices available to beneficiaries and are the basis for calculating beneficiary cost sharing and for beneficiary progression through the Part D drug benefit. The GCPDC is reported to CMS on PDE records; consequently, PDE records are the data source used for this calculation. For contract years 2006 and 2007, the API calculations were based on National Health Expenditure (NHE) prescription drug per capita estimates due to insufficient Part D program data availability; however, we transitioned to using PDE records for CY 2008 and future years.

The API calculation, where API represents the annual percentage increase for Part D expenditures for a given year, is comprised of two factors we refer to as: (1) an annual percentage trend (APT), and (2) a multiplicative update (MU) factor for prior-year revisions.

Mathematically, the formula is expressed as follows:

$$API = (APT) * (MU)$$

For a given payment year, the APT is the ratio of total per capita Part D drug expenditures in the 12-month period (August through July) prior to the given payment year (numerator) to the total per capita Part D drug expenditures two years prior to the given payment year (denominator).

For example, the APT for CY 2027 is equal to:

$$\frac{\text{Total per Capita Part D Drug Expenditures from August 2025 to July 2026}}{\text{Total per Capita Part D Drug Expenditures from August 2024 to July 2025}} - 1.0$$

(Numerator for previous year)
(Denominator for 2 years prior)

The MU factor is used to incorporate updated data for prior years into the calculation. We update data for prior years for two reasons: First, at the time the CMS Office of the Actuary calculates the API, actual, reasonably complete PDE data is typically only available for dates of service during the first 5 months of the measurement period (August–December). For the remainder of the measurement period (typically 7 months (January–July)), the costs must be estimated using historical data and actuarial experience. For example, for payment year 2027, the average per capita cost for August 2024–July 2025 (2 years prior) is calculated from submitted PDE data, while the average for August 2025–July 2026 (the year prior) is based on actual data from August 2025–

December 2025 and projections for January–July 2026. Second, PDE data may be resubmitted to make corrections or retroactive claim adjustments¹⁴ for activities such as coordination of benefits or changes in eligibility status for Part D or the Low-Income Subsidy program. Historically, we have used a retrospective period, typically 5 years, to update calculations to account for the impact of resubmissions that occur as part of Part D operations such as the annual Part D payment reconciliation under § 423.343 or a reopening of a reconciliation under § 423.346. We have found few to no resubmissions occur beyond a typical retrospective 5-year window.

The MU factor for a given year is the ratio of the product of the APTs for all

prior recorded years (since the first calculation in 2007), with the most recent 5 years revised and updated with the currently available data (numerator) to the product of APTs in prior recorded years as published in the previous year's Rate Announcement (denominator). As discussed in the preceding paragraphs, the MU factor has a 5-year retrospective window; however, we have historically included data since 2007 for informational purposes, as this historical data is the same in the numerator and the denominator and has no effect. To convert ratios to percentages, it is necessary to add 1.0 to each factor prior to entering them into the formula.

For example, the MU factor for CY 2027 is equal to:

$$\frac{[(1.00 + APT_{2025})(1.00 + APT_{2024}) \dots (1.00 + APT_{2007})]}{[(1.00 + APT_{CY26RA2025})(1.00 + APT_{CY26RA2024}) \dots (1.00 + APT_{CY26RA2007})]}$$

In this example, APT is the annual percentage trend, denoted with a subscript for the year of the data. The numerator is updated from CY 2020 through CY 2025, using the most recent data available when it is calculated in 2026, and the denominator uses data published in the CY 2026 Rate Announcement (published in April 2025).

Historically, the statutory parameters updated by the API have included the defined standard benefit deductible, initial coverage limit, annual OOP threshold, and the parameters for the LIS and RDS benefits. The IRA eliminated the coverage gap phase and beneficiary cost sharing above the annual OOP threshold; it also set the annual OOP threshold at \$2,000 for CY 2025. Given these changes, for CY 2025, only the defined standard deductible and LIS benefit parameters were updated using the API. For CY 2025 and subsequent years, no updates to the parameters for the initial coverage limit, maximum or minimum beneficiary cost sharing in the coverage gap or above the annual OOP threshold were necessary as the coverage gap phase and beneficiary cost sharing above the annual OOP threshold were eliminated. In CY 2026, the defined standard deductible, the annual OOP threshold, and the maximum copayment below the annual OOP threshold for low-income, full-subsidy-eligible beneficiaries with incomes between 100 and 150 percent of the FPL were updated using the API.

We propose to revise § 423.104(d)(5)(iv) by adding three paragraphs describing (1) the overall calculation of the annual percentage increase, or the API, in per capita Part D drug expenditures, (2) the calculation of the annual percentage trend, or the APT, and (3) the calculation of the multiplicative update factor, or the MU. We will continue to publish updates to the Part D benefit parameters calculated through these methodologies through the Advance Notice and Rate Announcement process described in section 1853(b) of the Act.

Calculation of the Annual Percentage Increase in CPI

Section 1860D–14(a)(4)(A) of the Act specifies that the annual percentage increase in CPI, a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services,¹⁵ is the annual percentage increase in the CPI (all items; U.S. city average) as of September of such previous year. As noted previously, the annual percentage increase in the CPI applies to the copayments for the lowest income dually eligible individuals (with incomes not exceeding 100 percent of the FPL) under section 1860D–14(a)(1)(D)(ii) of the Act, and is reflected at § 423.782(a)(2)(iii). The CPI is based on economic assumptions of the Consumer Price Index for All Urban Consumers (CPI–U), which is published by the Bureau of Labor Statistics. The method for calculating the annual

percentage increase in the CPI comprises two factors we refer to as: (1) an annual percentage trend; and (2) a multiplicative update factor for prior-year revisions.

While the other Part D benefit parameters are indexed using the API to track drug expenditure trends and maintain actuarial equivalence within the drug benefit structure, this parameter uses the CPI because it represents a fixed dollar copayment amount that needs to maintain its purchasing power relative to general inflation rather than specifically tracking drug cost inflation trends.

Mathematically, the formula is expressed as follows:

Annual Percentage Increase in CPI = $(APT) * (MU)$, where APT is the annual percentage trend, and MU is the multiplicative update factor for prior year revisions.

The APT consists of a year-over-year comparison of the CPI in the United States for all items, ending in the month of September. For a given payment year, it is the ratio of the CPI in the year ending the previous September (numerator) to the CPI for the year ending the September two years prior (denominator). To ensure that plan sponsors and CMS have sufficient time to incorporate cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, we include an estimate of the September CPI based on projections from the President's Budget in its

¹⁴ Medicare Prescription Drug Benefit Manual, Pub. 100–18, Chapter 14: Coordination of Benefits.

¹⁵ Consumer Price Index, <https://www.bls.gov/cpi/> (last visited Jun 17, 2025).

methodology to calculate the annual increase in the CPI for the 12-month

period ending in September prior to the applicable payment year.

For example, the annual percentage trend in the September CPI for CY 2027 is calculated as follows:

$$APT = \frac{\text{Projected September 2026 CPI}}{\text{Actual September 2025 CPI}}$$

The MU factor revises APTs in the September CPI to reflect updates (provided by the BLS) from the previously estimated September CPI to the actual reported September CPI. The MU factor for a given year is the ratio of the product of the APTs for all prior recorded years (since the first

calculation in 2007), with the most recent year updated with the currently available data (numerator) to the product of APTs in prior recorded years as published in the previous year's Rate Announcement (denominator). As mentioned in the preceding paragraphs, data since 2007 is included for

informational purposes. To convert the ratios to percentages, it is necessary to add 1.0 to each factor prior to entering them into the formula.

For example, the MU factor for CY 2027 is equal to—

$$\frac{[(1.00 + APT_{2025})(1.00 + APT_{2024}) \dots (1.00 + APT_{2007})]}{[(1.00 + APT_{CY26RA2025})(1.00 + APT_{CY26RA2024}) \dots (1.00 + APT_{CY26RA2007})]}$$

In this example, the numerator is updated from CY 2025 through CY 2026, using recent economic assumptions, and the denominator uses data published in the CY 2026 Rate Announcement (published in April 2025).

To implement the CPI calculation described previously in our regulations, we are proposing to revise § 423.782(a)(2)(iii)(A) to include a reference to a new paragraph (d), which we propose to add at the end of § 423.782. The new section at § 423.782(d) would comprise the general language of the statute, as well as add three subparagraphs describing: (1) the overall calculation of the annual percentage increase in CPI and specify the period ending in “September of such previous year,” (2) the calculation of the annual percentage trend, and (3) the calculation of the multiplicative update factor. We will continue to publish updates to the Part D benefit parameters calculated through these methodologies through the Advance Notice and Rate Announcement process described in section 1853(b) of the Act.

Technical Changes

We are proposing two technical changes to § 423.782(b). First, we propose to add a cross-reference to § 423.104(d)(5)(iv) to the provision at § 423.782(b)(1) to make clear that the annual percentage increase in average per capita aggregate expenditures that we use to calculate the deductible for certain low-income subsidy eligible individuals is calculated as provided in § 423.104(d)(5)(iv). Second, we propose to streamline the regulation text at § 423.782(b)(3) so that it directly cross

references the updated maximum copayment amounts that apply for years subsequent to 2006. Section 1860D–2(b)(4)(A)(i)(I) is implemented in regulation at § 423.104(d)(5)(i)(A)(2). We propose to replace the description in § 423.782(b)(3) of the annual process for updating maximum copayments with a cross reference to § 423.104(d)(i)(A)(2).

7. Changes to GCPDC and Allowable Reinsurance Cost Definitions To Include Costs Paid by the MDP (§ 423.308)

Section 1860D–15(b)(3) of the Act defines “gross covered prescription drug costs” as, “with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan . . . regardless of whether the coverage under the plan exceeds basic prescription drug coverage.” Section 1860D–15(b)(2) of the Act defines allowable reinsurance costs as “. . . such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan . . .” GCPDC and allowable reinsurance costs are defined and used at section 1860D–15(b) of the Act for the purpose of describing the methodology for calculating the reinsurance payment amount.

In the January 2005 Medicare Final Rule (70 FR 4194), we codified the

definition of “gross covered prescription drug costs” at § 423.308. This regulatory definition referred to “gross covered prescription drug costs” as “actually paid costs.” In the final rule that appeared in the **Federal Register** on April 12, 2023 (70 FR 22120), we revisited the regulatory definition of GCPDC by amending the definition at § 423.308 to remove the phrase “actually paid.” We made this change because the term “actually paid” has a specific meaning in Medicare Part D and is separately defined at § 423.308 to mean costs actually incurred by the plan that are net of direct and indirect remuneration (DIR), including discounts, rebates, or other price concessions typically received and applied after the point of sale (POS). However, unlike the statutory definitions of “allowable reinsurance costs” and “allowable risk corridor costs” at sections 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act, respectively, the statutory definition of “gross covered prescription drug costs” at section 1860D–15(b)(3) of the Act does not use the phrase “actually paid” or otherwise specify that such costs must be net of all DIR. As we explained in the December 2022 proposed rule (87 FR 79611), because the definition of “gross covered prescription drug costs” was codified in regulation for the sole purpose of describing the methodology for calculating the reinsurance payment amount, in using the phrase “actually paid” in the regulatory definition of “gross covered prescription drug costs,” We were incorporating a requirement from the statutory definition of “allowable reinsurance costs” to emphasize that DIR would be netted out

in the calculation of costs eligible for Part D reinsurance. As we explained in the proposed rule, the proposed revisions to the definition would not change the fact that Part D reinsurance is ultimately based on net drug costs or change the final reinsurance payment amount a Part D sponsor receives. Rather, allowable reinsurance costs would continue to be defined at § 423.308 as the subset of gross covered prescription drug costs actually paid.

Manufacturer discounts, among other costs, paid under the Coverage Gap Discount Program (as described in section 1860D–14A of the Act) were always included in the calculation of GCPDC. This policy was consistent with the statutory and regulatory definition of GCPDC, which generally requires the inclusion of all costs incurred under the plan, including those paid on behalf of the Part D beneficiary. The IRA sunset the Coverage Gap Discount Program as of January 1, 2025. As such, these costs are no longer included in the calculation of GCPDC. Section 11201(b)(3) of the IRA amended section 1860D–15(b)(3) of the Act in two places to also require the inclusion of manufacturer discounts paid under the Manufacturer Discount Program in the calculation of GCPDC (first, by specifying that the definition of GCPDC is subject to paragraph (2)(B) of section 1860D–15(b) of the Act and second, by adding language specifying that, in the case of an applicable drug, as defined at § 423.100, GCPDC shall be determined whether the costs are paid by the individual, under the plan, or by a manufacturer). Moreover, section 11201(b)(2) of the IRA also amended section 1860D–15(b)(2) of the Act to require the inclusion of manufacturer discounts paid under the Manufacturer Discount Program under section 1860D–14C of the Act in the calculation of allowable reinsurance costs in 2025.

In the Final CY 2025 Part D Redesign Program Instructions, under the requirement in section 11201(f) of the IRA that we use program instruction or other forms of program guidance to implement section 11201 of the IRA for 2025 and to mirror the statutory language in sections 1860D–15(b)(2) and (3) of the Act, as amended by the IRA, we stated that the regulatory definition of “gross covered prescription drug costs” at § 423.308 would be considered to have been revised for CY 2025 to include “all amounts paid by manufacturers under the Manufacturer Discount Program (as defined in section 1860D–14C of the Act).” Additionally, we stated that the regulatory definition of “allowable reinsurance costs” at § 423.308 would be considered to have

been revised for CY 2025 to include “the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined in section 1860D–14C(g)(2) of the Act) paid by manufacturers under the Manufacturer Discount Program (as defined in section 1860D–14C of the Act).”

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the policy with respect to the definitions of GCPDC and allowable reinsurance costs, also applied in CY 2026.

We propose to codify the policy that we established in the Final CY 2025 Part D Redesign Program Instructions for CY 2025 and applied via the Final CY 2026 Part D Redesign Program Instructions for CY 2026 with the limited modifications mentioned later in this section. Specifically, we propose that the regulatory definition of “gross covered prescription drug costs” at § 423.308 be revised to include “all amounts paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100).” We also propose to add the phrase “for years prior to 2025” before the phrase “amounts between the initial coverage limit and the out-of-pocket threshold” and the phrase “because the enrollee is between the initial coverage limit and the out-of-pocket threshold” to reflect that the coverage gap phase does not exist for 2025 and subsequent years. Additionally, we propose to revise the regulatory definition of “allowable reinsurance costs” at § 423.308 to include “the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined at § 423.100) paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100).”

8. Reinsurance Methodology (§ 423.329)

Section 1860D–15(b) of the Act, originally enacted into law by the MMA, sets forth rules for the calculation and payment of federal reinsurance subsidies for Part D plans. For years preceding CY 2025, the reinsurance amount for a Part D eligible individual was an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred after that individual reached the catastrophic phase of the benefit. In the January 2005 Medicare Final Rule, we codified this calculation at § 423.329(c)(1).

Under section 1860D–15(b)(2) of the Act, we make reinsurance payments to Part D plan sponsors based on the GCPDC that were actually paid during the coverage year. “Actually paid,” defined at § 423.308, means that the costs must be actually incurred by the Part D sponsor and must be net of any DIR. Each year, sponsors report their DIR to us as part of the annual DIR reporting process, and we use this information, along with cost data reported on PDE records, to allocate a portion of the DIR towards reducing allowable reinsurance costs. Historically, we allocated DIR to reduce allowable reinsurance costs and calculate final reinsurance subsidy payments in accordance with the methodology provided in the CY 2006 Advance Notice.

The IRA significantly modifies the reinsurance subsidy under the Part D benefit in CY 2025. Specifically, under section 1860D–15(b) of the Act, as amended by section 11201(b) of the IRA, in 2025, the reinsurance payment amount for a Part D beneficiary will decrease from 80 percent of the allowable reinsurance costs incurred after the beneficiary exceeds the annual OOP threshold to 20 percent for applicable drugs or 40 percent for drugs that are not applicable drugs.

Covered Part D drugs that are not applicable drugs and which are eligible for reinsurance payments amounts equal to 40 percent of the allowable reinsurance costs incurred include selected drugs (as defined in section 1192(c) of the Act and as we propose to define at § 423.100) during a price applicability period (as defined in section 1191(b)(2) of the Act and as we propose to define at § 423.100), as well as non-applicable drugs (as defined in section 130 of the Medicare Part D Manufacturer Discount Program Final Guidance and section II.C. of this proposed rule).

Therefore, a different calculation applies to applicable drugs versus non-applicable and selected drugs for the reinsurance payment amount, and the methodologies for calculating the reinsurance subsidy and allocating direct and indirect remuneration (DIR) towards reinsurance, must also be reconsidered.

In the Final CY 2025 Part D Redesign Program Instructions, we established a methodology to calculate the reinsurance subsidy separately for applicable and non-applicable drugs and allocate the share of DIR for applicable and non-applicable drugs based on their respective gross drug costs that fall in the catastrophic phase. The methodology otherwise aligns with

our historical approach for apportioning DIR.

Specifically, we stated that after the end of the coverage year, we would reconcile reinsurance subsidies for applicable drugs as follows:

- Identify incurred reinsurance costs for applicable drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for applicable drugs at the plan level.
- Allocate DIR for applicable drugs to incurred reinsurance costs for applicable drugs by applying the ratio of total DIR to total allowed costs. (The allocated DIR for reinsurance is referred to as “reinsurance DIR.”)
- Subtract reinsurance DIR for applicable drugs from incurred reinsurance costs for applicable drugs, then multiply the difference by 20 percent (the reinsurance payment amount percentage for applicable drugs).

Similarly, after the end of the coverage year, we stated that we would reconcile reinsurance subsidies for non-applicable drugs as follows:

- Identify incurred reinsurance costs for non-applicable drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for non-applicable drugs at the plan level.
- Allocate DIR for non-applicable drugs to incurred reinsurance costs for non-applicable drugs by applying the ratio of total DIR to total allowed costs.
- Subtract reinsurance DIR for non-applicable drugs from incurred reinsurance costs for non-applicable drugs, then multiply the difference by 40 percent (the reinsurance payment amount percentage for non-applicable drugs).

The sum of the adjusted reinsurance amounts for applicable and non-applicable drugs will then be reconciled with prospective reinsurance payment amounts made to plans during the coverage year.

In the Final CY 2026 Part D Redesign Program Instructions, we updated the methodology applied in CY 2025 to account for selected drugs, as the selected drug subsidy program begins in 2026. Specifically, we stated that, for CY 2026, we would calculate the reinsurance subsidy separately for applicable drugs. Because the percentage of allowable reinsurance costs to calculate the reinsurance payment amount for a Part D beneficiary is the same for non-applicable and selected drugs, the reinsurance subsidy for non-applicable and selected drugs would be calculated together. Additionally, we stated that, for CY

2026, we would allocate the share of DIR for applicable drugs and non-applicable and selected drugs based on their respective share of gross drug costs that fall in the catastrophic phase.

After the end of CY 2026, we stated that we would reconcile reinsurance subsidies for non-applicable and selected drugs as follows:

- Identify incurred reinsurance costs for non-applicable and selected drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for non-applicable and selected drugs at the plan level.
- Allocate DIR for non-applicable and selected drugs to incurred reinsurance costs for non-applicable and selected drugs by applying the ratio of total DIR to total allowed costs. (The allocated DIR for reinsurance is referred to as “reinsurance DIR.”)
- Subtract reinsurance DIR for non-applicable and selected drugs from incurred reinsurance costs for non-applicable and selected drugs, then multiply the difference by 40 percent (the reinsurance payment amount percentage for non-applicable and selected drugs).

The sum of the adjusted reinsurance amounts for applicable drugs and non-applicable and selected drugs for CY 2026 will then be reconciled with prospective reinsurance payment amounts made to plans during the coverage year. To determine the appropriate category (applicable, non-applicable, or selected) for drugs, we stated we would use the 11-digit NDC submitted on each PDE record and assign it with an applicable, non-applicable, or selected designation based on the marketing category listed for that NDC in the U.S. Food and Drug Administration (FDA)’s NSDE file used for PDE processing and the list of NDCs referenced in the Medicare Drug Price Negotiation Program guidance.

For CY 2026, the calculation formulas for applicable drugs are:

Reinsurance DIR for applicable drugs =
 $(\text{total DIR} / \text{total allowed costs}) \times$
 incurred reinsurance costs for
 applicable drugs.

Adjusted reinsurance for applicable
 drugs = $(\text{incurred reinsurance costs}$
 for applicable drugs – reinsurance
 DIR for applicable drugs) $\times 0.20$.

For CY 2026, the calculation formulas for non-applicable and selected drugs are:

Reinsurance DIR for non-applicable and
 selected drugs = $(\text{total DIR} / \text{total}$
 allowed costs) $\times$ incurred
 reinsurance costs for non-applicable
 and selected drugs.

Adjusted reinsurance for non-applicable
 and selected drugs = $(\text{incurred}$
 reinsurance costs for non-applicable
 and selected drugs – reinsurance
 DIR for non-applicable and selected
 drugs) $\times 0.40$.

In this proposed rule, we propose to codify at § 423.329 the policies we established in the Final CY 2025 Part D Redesign Program Instructions for CY 2025 and the Final CY 2026 Part D Redesign Program Instructions for CY 2026 with respect to the reinsurance methodology without modification. Specifically, we propose to redesignate paragraph (c)(1) as paragraph (c)(1)(i) and revise the introductory language to state “general rule for years preceding 2025” and add a new paragraph (c)(1)(ii) to codify the rules described previously for 2026 and future years.

9. Selected Drug Subsidy (§§ 423.265, 423.315, 423.329, 423.343)

Section 11201 of the IRA added section 1860D–14D to the Act, creating a new selected drug subsidy program, which began in CY 2026. Under the selected drug subsidy program, the Secretary must, periodically and on a timely basis, provide Part D plan sponsors with a subsidy for selected drugs, as defined under section 1192(c) of the Act, equal to 10 percent of the drug’s negotiated price. The selected drug subsidy applies to a covered Part D drug that would otherwise meet the definition of an applicable drug but for being a selected drug under the Medicare Drug Price Negotiation Program during a price applicability period. The subsidy is paid on behalf of an applicable beneficiary who is enrolled in a PDP or an MA–PD plan, has not incurred costs that are equal to or exceed the annual OOP threshold, and is dispensed a selected drug.

Under the selected drug subsidy program, once an enrollee incurs costs exceeding the annual deductible specified in section 1860D–2(b)(1) of the Act (that is, the deductible under the defined standard benefit) the selected drug subsidy is available in the initial coverage phase of the benefit. The selected drug subsidy lowers Part D plan sponsor liability on the negotiated price of the drug.

Because of the intertwined structure and wording of the Manufacturer Discount Program and selected drug subsidy program provisions at sections 1860D–14C and 1860D–14D of the Act, we interpret the statute as establishing the selected drug subsidy as a substitute for the Manufacturer Discount Program discount for a covered Part D drug that would otherwise meet the definition of an applicable drug but for being a

selected drug under the Medicare Drug Price Negotiation Program during a price applicability period. As such, we propose to treat claims that are subject to the selected drug subsidy as coterminous with claims that would qualify for applicable discounts under the Manufacturer Discount Program, but for the drug's status as a selected drug during a price applicability period. In other words, the selected drug subsidy will apply if the selected drug that otherwise would be an "applicable drug" would have received an applicable discount under the Manufacturer Discount Program for the particular claim at issue under the rules of the Manufacturer Discount Program. Conversely, the selected drug subsidy will not apply if the applicable discount under the Manufacturer Discount Program otherwise would not have applied to that particular claim. For example, as discussed in section II.C. of this proposed rule, certain claims involving an applicable drug, such as Medicare Secondary Payer claims, are not subject to discounts under the Manufacturer Discount Program; in these situations, the selected drug subsidy would also not apply.

Because certain actual expenses can only be fully known after all costs have been incurred for a payment year, we make final payment for these costs after a coverage year after obtaining all the information necessary to determine the amount of payment. We currently make monthly prospective payments of certain estimated costs submitted with bids, including reinsurance costs and low-income cost-sharing subsidy (LICS) costs, to mitigate cash-flow concerns that plans could experience if such payments were made wholly on a retrospective basis.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that similar concerns suggested that we should also make monthly prospective payments for the selected drug subsidy program. We accordingly established a process where Part D plan sponsors are required to submit estimates of selected drug subsidy amounts with their annual bids and we pay Part D plan sponsors prospective selected drug subsidy amounts equal to these estimated amounts. We use the actual selected drug subsidy amounts that Part D plan sponsors report on PDE data to determine actual costs incurred for selected drug subsidy payments.

After the deadline for PDE submissions for a year, we will calculate the difference between the prospective payments made by us to the Part D plan sponsor and the actual payments made by the Part D plan sponsor to determine

a selected drug subsidy reconciliation amount. We will make a lump-sum adjustment to monthly payments based on the calculated reconciliation amount in the same manner as is done for other Part D reconciliation payments. Specifically, we will recover payments made for a coverage year if prospective selected drug subsidy payments exceed the selected drug subsidy costs actually incurred by the plan or if the Part D plan sponsor does not provide the data requested by us to verify the plan's actual selected drug subsidy amount; similarly, we will make a lump sum payment if the actually incurred subsidy amount exceeds the prospective selected drug subsidy payments.

In this proposed rule, we propose to codify the policies we established in the Final CY 2026 Part D Redesign Program Instructions with respect to the selected drug subsidy for 2026 and subsequent years without modification. Specifically, we propose to codify at new § 423.265(d)(2)(vi) a requirement that assumptions regarding selected drug subsidy amounts payable be included in Part D bids submitted to us. We also propose to codify at new § 423.315(h) that we would provide prospective selected drug subsidy payments on a monthly basis. We also propose to codify at new § 423.329(e) the determination of selected drug subsidy payments. Finally, we propose to codify at § 423.343(e) that we would make final payment for selected drug subsidy payments after a coverage year after obtaining all information necessary to determine the amount of payment.

10. Technical Correction—Retroactive Adjustments and Reconciliations (§§ 423.336 and 423.343)

In the course of this rulemaking, we noticed the need for a technical correction at § 423.343(d)(2). The final sentence of this paragraph states that in the event Part D sponsors do not provide adequate data to us for the calculation of risk corridor payments, we assume that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount. This sentence is incorrectly placed in § 423.343, which describes payments of low-income cost-sharing subsidies, and should instead be placed in § 423.336, which describes risk sharing arrangements. Thus, we propose to revise § 423.343 to remove this sentence and revise § 423.336(c) to add this sentence in its proper context.

11. Base Beneficiary Premium (§ 423.286)

Section 1860D–13(a)(2) of the Act, as established by the MMA, describes the

statutory formula for calculating plan-specific basic Part D premiums under the Part D program. The national base beneficiary premium (BBP) is the starting point for calculating a plan-specific basic Part D premium. Prior to the enactment of the IRA, the BBP was calculated as the product of the beneficiary premium percentage and the national average monthly bid amount. The beneficiary premium percentage ("applicable percentage") is a fraction, with a numerator of 25.5 percent and a denominator equal to 100 percent minus a percentage equal to (i) the total reinsurance payments that we estimate will be paid for the coverage year, divided by (ii) that amount plus the total payments that we estimate will be paid to Part D plans based on the standardized bid amount during the year, taking into account amounts paid by both CMS and plan enrollees. In the January 2005 Medicare Final Rule, we codified the statutory formula for calculating the BBP at § 423.286.

Section 11201 of the IRA amended section 1860D–13(a)(2) of the Act such that the statutory formula described in the preceding paragraph would apply subject to a newly added section 1860D–13(a)(8)(A) of the Act, which states that, for a prescription drug plan for a month in 2024 through 2029, the BBP shall be equal to the lesser of the BBP for the preceding year increased by 6 percent or the amount computed under the formula described in section 1860D–13(a)(2) of the Act. In the Advance Notice of Methodological Changes for CY 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (2024 Advance Notice)¹⁶ and the July 31, 2023 HPMS memorandum titled, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information",¹⁷ we stated that it would calculate the BBP as the lesser of the prior year's BBP increased by 6 percent, or the BBP as it would have been calculated if the IRA's premium stabilization provision had not been enacted, to determine the CY 2024 BBP. In the July 29, 2024, HPMS memorandum titled, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," we applied the revised formula described in this paragraph to determine the CY 2025 BBP.

In this proposed rule, we propose to codify the statutory amendments to section 1860D–13(a) of the Act.

¹⁶ <https://www.cms.gov/files/document/2024-announcement-pdf.pdf>.

¹⁷ <https://www.cms.gov/files/document/july-29-2024-parts-c-d-announcement.pdf>.

Specifically, we propose to redesignate § 423.286(b) as § 423.286(b)(1) and codify the BBP formula for 2024 through 2029 at new § 423.286(b)(2).

12. Low-Income Cost-Sharing Subsidy (§ 423.782)

The Part D low-income subsidy (LIS) helps individuals with Medicare who meet certain statutory income and resource criteria pay for prescription drugs and lowers the costs of prescription drug coverage. Prior to the enactment of the IRA, individuals who qualified for the full LIS received assistance to pay their full premiums and deductibles (in certain Part D plans) and have reduced cost sharing. Individuals who qualified for the partial LIS paid reduced premiums (on a sliding scale based on their income) and also had reduced deductibles and cost sharing. Section 11404 of the IRA amended section 1860D–14 of the Act to expand eligibility for the full LIS to individuals who are determined to have incomes below 150 percent of the FPL and who meet either the resource standard in paragraph (3)(D) or paragraph (3)(E) of section 1860D–14(a) of the Act, with respect to plan years beginning on or after January 1, 2024. Thus, beginning in CY 2024, individuals who previously would have qualified for the partial subsidy now receive the full LIS.

In the final rule titled, “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” which appeared in the April 12, 2023 **Federal Register** (88 FR 22120), and therewithin, we codified the applicable rules under §§ 423.773 and 423.780 to expand eligibility for the LIS under Part D. In this rule, we propose to also amend the eligibility criteria for LIS cost sharing reductions at § 423.782 to align with the IRA’s amendments to section 1860D–14(a)(1) of the Act and the changes to §§ 423.773 and 423.780. Specifically, we propose to update the FPL limit specified in § 423.782(a)(2)(i)(B) to 150 percent for plan years beginning on or after January 1, 2024.

In addition, we propose to amend paragraph (a)(2) of § 423.782 to state that for years preceding 2025, LIS cost sharing reductions applied to covered Part D drugs obtained after the initial coverage limit and below the OOP limit.

13. Retiree Drug Subsidy Parameters (§§ 423.882 and 423.884)

Section 1860D–22 of the Act provides for subsidy payments to sponsors of qualified retiree prescription drug plans, provided that the employment-based retiree health coverage is at least actuarially equivalent to the standard prescription drug coverage under Medicare Part D. In the January 2005 Medicare Final Rule, we established regulations at 42 CFR part 423 Subpart R to, in part, determine which group health plans may qualify as qualified retiree prescription drug plans and, therefore, be eligible to receive retiree drug subsidy payments for a qualifying covered retiree.

Per section 1860D–22(a)(2)(A) of the Act, qualified retiree prescription drug plans are required to annually attest that the actuarial value of prescription drug coverage under the plan (as described in section 1860D–11(c) of the Act) is at least equal to the actuarial value of standard prescription drug coverage, not taking into account the value of any discount provided under the Manufacturer Discount Program as established in section 1860D–14C of the Act, and disclose that coverage under the plan is creditable in accordance with section 1860D–13(b)(6)(B) of the Act.

In the Final CY 2025 Part D Redesign Program Instructions, we addressed the implications of the amendments to the parameters of the standard prescription drug coverage made by the IRA for the retiree drug subsidy parameters described at Subpart R and summarized the IRA policies in effect for 2025 that are considered in determining the actuarial value of the defined standard benefit. While the IRA amends the parameters of the standard prescription drug coverage and makes other changes to the Part D benefit, we stated that there are no changes to the requirements for qualified retiree prescription drug plans.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the guidance related to the retiree drug subsidy parameters, also applied in CY 2026.

The majority of the IRA policies in effect for CY 2027 and subsequent years do not require updates to Subpart R; however, there are certain conforming edits required to reflect the proposed revisions to the definitions of “gross covered prescription drug costs” and “allowable reinsurance costs” as well as revisions needed to reflect the sunset of the Coverage Gap Discount

Program and the establishment of the Manufacturer Discount Program. Specifically, we propose to revise the definitions of “gross covered retiree plan-related prescription drug costs” and “allowable retiree costs” at § 423.882 to reflect the proposed revisions to the definitions of “gross covered prescription drug costs” and “allowable reinsurance costs” at § 423.308. We also propose to replace all references in § 423.884(d) to “not taking into account the value of any discount or coverage provided during the coverage gap” with the statement “for years prior to 2025, not taking into account the value of any discount or coverage provided during the coverage gap and for 2025 and subsequent years, not taking into account the value of any discount provided under the Manufacturer Discount Program.”

14. Medical Loss Ratio (§ 423.2420)

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the final rule titled “Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” which appeared in the May 23, 2013 **Federal Register** (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule), in which we codified the MLR requirements for MA organizations and Part D prescription drug plan sponsors (“Part D sponsors”) (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X.

Generally, the MLR for each Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. The MLR for a Part D contract reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees for Part D prescription drugs and on quality initiatives that meet the requirements at § 423.2430. The percentage of revenue that is used for other items such as administration, marketing, and profit is excluded from the numerator of the MLR for MA and

Part D (see §§ 423.2401; 423.2420(b)(4); 423.2430(b)).

The MLR regulations at § 423.2420(c) specify that the following Part D plan payments from the federal government are included in the MLR denominator: the direct subsidy, prospective Federal reinsurance subsidy, reconciliation adjustments to the Federal reinsurance subsidy, low-income premium subsidy (LIPS) amount, and risk corridor payments. In the May 2013 Medicare MLR final rule, we explained that we viewed LICs and Coverage Gap Discount Program payments as pass-through payments for which plans do not retain any liability, and that these amounts should therefore be excluded from the MLR calculation (78 FR 31290); accordingly, LICs and Coverage Gap Discount Program payments are excluded from both the MLR numerator and denominator.

The IRA introduced new categories of Part D plan payments from the Federal government. These include the Manufacturer Discount Program payment, the Inflation Reduction Act Subsidy Amount (IRASA), and the selected drug subsidy payment. The payment process for the Manufacturer Discount Program payments includes a cost-based reconciliation intended to make Part D sponsors whole for the manufacturer discount amounts they advance on behalf of the manufacturer. The IRASA is a Part D payment specific to CY 2023 that we provided to Part D plan sponsors. This temporary retrospective subsidy was paid to Part D plans for the reduction in cost sharing and elimination of the deductible for ACIP-recommended adult vaccines and covered insulin products during the 2023 plan year (that is, to cover the difference between the beneficiary cost sharing for the covered insulin, or ACIP-recommended adult vaccine, under the plan's 2023 benefit design, and the applicable statutory maximum cost sharing (\$35 for a one month-supply of covered insulin products and \$0 for vaccines)). Finally, under the selected drug subsidy program, the government provides a subsidy to Part D plan sponsors for selected drugs dispensed to enrollees in the initial coverage phase.

In the Final CY 2025 Part D Redesign Program Instructions, we stated that for CY 2025 and prior years, the new Part D plan payments for the Manufacturer Discount Program and IRASA are excluded from the denominator of the MLR calculation, and associated expenditures are excluded from the numerator of the MLR calculation. In the Final CY 2026 Part D Redesign Program Instructions, we stated that the new Part D plan payments for the

selected drug subsidy are excluded from the denominator of the MLR calculation, and associated expenditures are excluded from the numerator of the MLR calculation. In the Final CY 2026 Part D Redesign Program instructions, we applied certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the treatment of the Manufacturer Discount Program payments, in CY 2026.

In this proposed rule, we propose to codify for CY 2027 and subsequent years the policies established in the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions with respect to the treatment of the Manufacturer Discount Program payments, IRASA, and selected drug subsidy program payments for MLR purposes. These policies are currently in effect. Specifically, we propose to codify the exclusion of the Manufacturer Discount Program payments, IRASA, and selected drug subsidy program payments at § 423.2420(b)(4)(iii), (iv), and (v) respectively.

15. Severability

The Medicare Part D redesign provisions proposed herein are separate and severable from one another. If any of these provisions, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it is our intention that such provision shall be severable from this rule and not affect the remainder thereof, or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

B. Medicare Coverage Gap Discount Program

The Patient Protection and Affordable Care Act (Pub. L. 111–148) amended Title XVIII of the Act by adding sections 1860D–14A and 1860D–43, establishing the Medicare Coverage Gap Discount Program. The Coverage Gap Discount Program, which began on January 1, 2011, was initially implemented through program instruction, and program requirements were codified in the “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes” final rule (77 FR 22072) under subpart W of 42 CFR part 423.

The Coverage Gap Discount Program made manufacturer discounts available at the point of sale (POS) to Part D enrollees who are not eligible for the low-income subsidy (LIS) under section

1860D–14 of the Act when receiving applicable drugs (as defined at § 423.100) while in the coverage gap phase of the Part D benefit. Under Coverage Gap Discount Program rules, pharmaceutical manufacturers were required to enter into a Coverage Gap Discount Program agreement with CMS in order for their applicable drugs to be covered under Part D. In general, the discount was 70 percent of the negotiated price (as defined at § 423.2305) of the applicable drug.

The Inflation Reduction Act of 2022 (Pub. L. 117–169) (IRA) made significant changes to the Part D benefit design, which are discussed in more detail in section II.A. of this proposed rule. These changes included eliminating the coverage gap phase of the Part D benefit after 2024 and adding section 1860D–14C to the Act, which established the Manufacturer Discount Program, under which manufacturers pay discounts for applicable drugs when dispensed to Part D enrollees during the initial and catastrophic coverage phases. Our proposal to codify the Manufacturer Discount Program is discussed in section II.C. of this proposed rule.

Consistent with the elimination of the coverage gap phase of the Part D benefit, section 11201 of the IRA added section (h) to section 1860D–14A of the Act, which sunset the Coverage Gap Discount Program and terminated all Coverage Gap Discount Program agreements, effective January 1, 2025. Section 1860D–14A(h)(2) of the Act further specifies that the provisions of section 1860D–14A of the Act, including all responsibilities and duties under such agreements continue to apply with respect to applicable drugs dispensed prior to January 1, 2025. Accordingly, we propose to amend § 423.2300 by adding a new paragraph to specify that the requirements of Subpart W apply before January 1, 2025 and, with respect to applicable drugs dispensed prior to that date, continue to apply on and after January 1, 2025. To make this change, we propose to redesignate the existing text of § 423.2300 as paragraph (a) and redesignate existing paragraphs (a) through (h) as § 423.2300(a)(1) through (8), respectively. We propose to add the new text at § 423.2300(b). We also propose to revise § 423.2315(c)(2) to reflect the sunset of the Coverage Gap Discount Program by limiting this provision specifying the effective date of a Coverage Gap Discount Program agreement to 2012 and subsequent years prior to 2025. Finally, in accordance with section 1860D–14A(h)(1) of the Act, we propose to amend § 423.2345 by adding a new paragraph (f) to specify

that, subject to § 423.2300(b), as redesignated, all Coverage Gap Discount Program agreements under this subpart are terminated as of January 1, 2025.

As discussed in more detail in section II.C. of this proposed rule, “discounted price” is defined at section 1860D–14A(g)(4) of the Act for purposes of the Coverage Gap Discount Program and at section 1860D–14C(g)(4) of the Act for purposes of the Manufacturer Discount Program. Because the percentage of the negotiated price that the manufacturer agrees to pay is different under the two programs, the statutory term “discounted price” as well as its corresponding regulatory term “applicable discount” have different meanings between the two programs. To address the programmatic difference, we propose to revise the regulation text at § 423.2305 to clarify that the definitions in this section apply only for purposes of the Coverage Gap Discount Program. Further, we propose to revise the definition of “applicable discount” at § 423.2305 to specify that it refers to 50 percent of the negotiated price with respect to a plan year before 2019 and 70 percent of the negotiated price with respect to plan year 2019 through plan year 2024. This clarification further distinguishes the definition of “applicable discount” at § 423.2305 under the Coverage Gap Discount Program from the definition of “applicable discount” (proposed at § 423.2712 as part of this proposed rule) under the Manufacturer Discount Program.

Lastly, for clarity and readability, we propose technical changes throughout Subpart W to replace the shorthand term “Discount Program” with “Coverage Gap Discount Program,” to better distinguish it from the Manufacturer Discount Program.

C. Medicare Part D Manufacturer Discount Program

1. Background

The Medicare Part D Manufacturer Discount Program (Manufacturer Discount Program) was enacted into law in section 11201 of the Inflation Reduction Act of 2022, Public Law 117–169 (IRA) and codified in sections 1860D–14C and 1860D–43 of the Act. Section 11201(f) of the IRA directed the Secretary to implement the Manufacturer Discount Program by program instruction or other forms of program guidance for 2025 and 2026. In accordance with the law, on November 17, 2023, CMS released the Medicare Part D Manufacturer Discount Program Final Guidance. On December 20, 2024, we released the Revised Medicare Part

D Manufacturer Discount Program Final Guidance (Manufacturer Discount Program Final Guidance).¹⁸

The IRA made significant changes to the Part D benefit, which are discussed in detail in section II.A. of this proposed rule. The IRA eliminated the coverage gap phase of the Part D benefit after 2024 and added subsection (h) to section 1860D–14A of the Act, which sunset the Coverage Gap Discount Program and terminated all Coverage Gap Discount Program agreements effective January 1, 2025. Our proposal to update the Part D regulations to reflect the statutory sunset of the Coverage Gap Discount Program and termination of Coverage Gap Discount Program agreements is discussed in section II.B. of this proposed rule.

In this proposed rule, we would codify the Manufacturer Discount Program Final Guidance, with the refinements and changes discussed herein, to be effective beginning CY 2027. Under the Manufacturer Discount Program, for applicable drugs and selected drugs to be coverable under Part D, manufacturers of such drugs are required to enter into a Manufacturer Discount Program agreement with CMS and agree to provide discounts on their applicable drugs when dispensed to Part D enrollees who are in the initial and catastrophic coverage phases of the Part D benefit. Similar to the Coverage Gap Discount Program which the Manufacturer Discount Program replaces, the discounts under the Manufacturer Discount Program are advanced at the point of sale by the Part D plan sponsor, and manufacturers are invoiced quarterly based on the amounts submitted by plan sponsors on Prescription Drug Event (PDE) records. CMS provides prospective payments to plan sponsors to ensure they are able to advance the discounts and adjusts the payments through an annual reconciliation.

Unlike the Coverage Gap Discount Program, discounts under the Manufacturer Discount Program generally reduce the amount the Part D sponsor pays for the drug versus reducing the out-of-pocket amount for the enrollee, and discounts are paid for all Part D enrollees who have exceeded the annual Part D deductible specified in section 1860D–2(b)(1) of the Act. While the discounts are a lower percentage of the negotiated price of the applicable drug than under the Coverage Gap Discount Program (10 percent in the initial coverage phase and 20

percent in the catastrophic coverage phase), they continue through the end of the plan year once the enrollee exceeds the deductible. The discount percentages manufacturers are required to pay are phased in over the first several years of the program for manufacturers that meet statutory criteria for specified manufacturers and specified small manufacturers.

Many of the other policies currently in effect pursuant to the Manufacturer Discount Program Final Guidance, which we propose to codify in this rule, mirror longstanding policies under the Coverage Gap Discount Program, including use of a third party administrator (TPA) to facilitate program operations such as invoicing and payment, use of the Health Plan Management System (HPMS) to execute agreements and house data, and the manufacturer dispute resolution process. All of these policies are discussed in more detail later in this section.

2. Basis and Scope (§ 423.2700)

We propose to codify the requirements for the Manufacturer Discount Program under sections 1860D–14C and 1860D–43 of the Act as new subpart AA of part 423. Proposed § 423.2700(a) and (b) set forth the basis and scope, respectively.

We propose a conforming change at § 423.1 to incorporate section 1860D–14C of the Act into the scope of part 423.

3. Definitions (§§ 423.100, 423.1002, 423.2305, and 423.2704)

In this proposed rule, we propose to codify the definition of frequently used terms consistent with section 1860D–14C of the Act or established in the Manufacturer Discount Program Final Guidance, as well as new definitions based on the policies in this proposed rule.

Several of these terms are also used for purposes of the Coverage Gap Discount Program. In some cases, the same term has a different meaning for the Manufacturer Discount Program than for the Coverage Gap Discount Program because of differences in the programs reflected in sections 1860D–14C and 1860D–14A of the Act, respectively. Where possible under the statutory requirements, we propose to use the same terms, defined in the same way, for both programs. Because some of the terms are applicable to both subpart W and proposed subpart AA, we propose to revise certain definitions in existing §§ 423.100, 423.1002, and 423.2305, move certain definitions from § 423.2305 to § 423.100 with revisions

¹⁸ Available at: <https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf>.

as necessary to comply with relevant statutory requirements, and add new definitions for purposes of the Manufacturer Discount Program at proposed § 423.2704.

At § 423.100, we propose to revise a number of existing definitions as discussed below.

- “Applicable beneficiary”;

We propose to revise the definition of “applicable beneficiary” to reflect the statutory definition of such term under the Coverage Gap Discount Program and the Manufacturer Discount Program. Specifically, we propose adding that for the purposes of the Coverage Gap Discount Program, applicable beneficiary means an individual who on the date of dispensing a covered Part D drug is not entitled to an income-related subsidy under section 1860D–14(a) of the Act; has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year; has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and has a claim that is within the coverage gap or straddles or spans the coverage gap. We also propose adding to the definition that for the purposes of the Manufacturer Discount Program, applicable beneficiary means an individual who on the date of dispensing a covered Part D drug has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that exceed the annual deductible specified in section 1860D–2(b)(1) of the Act.

- “Applicable drug”;

We propose to modify the existing definition of “applicable drug” to specify that compounded drug products (as described in § 423.120(d)) containing an applicable drug are excluded. This proposed change would codify both longstanding CMS policy under the Coverage Gap Discount Program that excluded compounds as well as the policy established in section 40.1 of the Manufacturer Discount Program Final Guidance. As stated in the guidance, while plans may cover compounds that include at least one Part D ingredient, and that ingredient would be an applicable drug if dispensed on its own, we believe that the applicable drug determination must be made with respect to the compound as a whole. Because the compound as a whole is not approved under a New Drug Application (NDA) or Biologic Licensing Application (BLA), a compound does not meet the definition of an applicable drug.

Further, for the purposes of the Manufacturer Discount Program, we propose to clarify that applicable drug also includes a Part D drug that is provided to a particular applicable beneficiary as a transition fill under § 423.120(b)(3) or as an emergency supply as may be required for an applicable beneficiary who is a long-term care resident. This clarification would codify our longstanding approach under the Coverage Gap Discount Program where, in practice, such fills have been treated as meeting the definition of “applicable drug.”

Finally, in accordance with the statutory definition of “applicable drug” at section 1860D–14C(g)(2) of the Act and the Manufacturer Discount Program Final Guidance, we further propose to specify in the definition of “applicable drug” that, for the purposes of the Manufacturer Discount Program, an applicable drug is not a selected drug during a price applicability period with respect to such drug.

We propose to add definitions for the following terms at § 423.100:

- “Applicable discount”;

At § 423.100, we propose to add a definition of “applicable discount” that identifies the separate programmatic definitions of such term for the Coverage Gap Discount Program and the Manufacturer Discount Program. Specifically, we propose to define “applicable discount” as, for purposes of the Coverage Gap Discount Program, having the meaning set forth at § 423.2305, and for purposes of the Manufacturer Discount Program, the meaning set forth at § 423.2712.

- “Applicable number of calendar days”;

We propose to remove the definition of “applicable number of calendar days” from § 423.2305 and add it at § 423.100. This definition would apply to both the Coverage Gap Discount Program and the Manufacturer Discount Program.

- “Date of dispensing”;

We propose to remove the existing definition of “date of dispensing” from § 423.2305 and add it, with revisions, at § 423.100. Specifically, we propose to add at the end of the definition, “For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.” This proposed revision is consistent with the definition of “date of dispensing” used in the Manufacturer Discount Program Final Guidance and with criteria established under § 423.2325(g) for the Coverage Gap Discount Program.

- “Labeler code”;

We propose to remove the existing definition of “labeler code” from § 423.2305 and add it, with revisions, at § 423.100. Specifically, we propose to remove the phrase “Food and Drug Administration” for conciseness and accuracy.

- “Manufacturer”;

We propose to remove the existing definition of “manufacturer” from § 423.2305 and add it at § 423.100 with a revision removing the phrase “Discount Program” and adding in its place the phrase “Coverage Gap Discount Program and the Manufacturer Discount Program” for accuracy.

- “Manufacturer Discount Program”;

We propose to define “Manufacturer Discount Program” as the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

- “Manufacturer Discount Program agreement”;

We propose to define “Manufacturer Discount Program agreement” as the agreement described at section 1860D–14C(b) of the Act.

- “Medicare Coverage Gap Discount Program”;

We propose to remove the definition of “Medicare Coverage Gap Discount Program” from § 423.2305 and add it at § 423.100, with revisions to remove the phrase “Program (or Discount Program)” and add in its place the phrase “Program (or Coverage Gap Discount Program)”.

- “Medicare Coverage Gap Discount Program agreement”;

We propose to remove the definition of “Medicare Coverage Gap Discount Program agreement” from § 423.2305 and add it at § 423.100 with revisions to remove the phrase “Program agreement (or Discount Program agreement)” and add in its place the phrase “Program agreement (or Coverage Gap Discount Program agreement)”.

- “National Drug Code (NDC)”;

We propose to remove the definition of “National Drug Code” from § 423.2305 and add it at § 423.100 with revisions to remove the phrase “the product” and add in its place the phrase “the product’s manufacturer, product”. This proposed revision aligns with the definition of NDC used in the Manufacturer Discount Program Final Guidance.

- “Non-applicable drug”;

We propose to define “non-applicable drug” to mean any Part D drug that is not an applicable drug and not a selected drug during a price applicability period with respect to such drug.

- “Price applicability period”;

We propose to define “price applicability period” as having the

meaning given such term in section 1191(b)(2) of the Act and any applicable regulations and guidance.

- “Selected drug”;

We propose to define “selected drug” as having the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance. Such definition aligns with the definition used in the Manufacturer Discount Program Final Guidance.

- “Third Party Administrator (TPA)”.

We propose to add at § 423.100 the definition of “Third Party Administrator” that we propose to remove from § 423.2305, with revisions. Specifically, we propose to remove the phrase “section 1860D–14A of the Act” and add in its place the phrase “sections 1860D–14A and 1860D–14C of the Act”.

At § 423.1002, we propose to revise the existing definition of “affected party” to account for the definition of “manufacturer” under the Coverage Gap Discount Program and the definition of “agreement holder” under the Manufacturer Discount Program. Specifically, we propose that affected party means any Part D sponsor or, for purposes of the Coverage Gap Discount Program, any manufacturer (as defined in § 423.100), or, for purposes of the Manufacturer Discount Program, any manufacturer that is an agreement holder (as defined in § 423.2704), impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and “party” means the affected party or CMS, as appropriate.

We propose to remove the following definitions from § 423.2305 because, as noted previously, we propose to add definitions for such terms at § 423.100, for purposes of incorporating the Manufacturer Discount Program:

- “Applicable number of calendar days”;
- “Date of dispensing”;
- “Labeler code”;
- “Manufacturer”;
- “Medicare Coverage Gap Discount Program”;
- “Medicare Coverage Gap Discount Program Agreement”;
- “National Drug Code (NDC)”;
- “Third Party Administrator (TPA)”.

At § 423.2704, we propose to define the following terms for purposes of proposed subpart AA and the Manufacturer Discount Program:

- “Agreement holder”;

We propose to define “agreement holder” as a manufacturer that has executed and has in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

- “Applicable discount”;

We propose to define “applicable discount” as having the meaning set forth at § 423.2712.

- “Applicable LIS percent”;

We propose to define “applicable LIS percent” as having the meaning set forth at § 423.2712(d)(1).

- “Applicable small manufacturer percent”;

We propose to define “applicable small manufacturer percent” as having the meaning set forth at § 423.2712(d)(2).

- “Covered Part D drug”;

We propose to define “covered Part D drug” as having the meaning set forth at § 423.100.

- “Dispute submission deadline”;

We propose to define “dispute submission deadline” as the date that is 60 calendar days from the date of the invoice containing the information that is the subject of the agreement holder’s dispute.

- “Negotiated price”;

We propose to define “negotiated price” as having the meaning set forth at § 423.100, and with respect to an applicable drug under the Manufacturer Discount Program, such negotiated price includes any dispensing fee and, if applicable, any vaccine administration fee and sales tax.

- “Network pharmacy”;

We propose to define “network pharmacy” as having the meaning set forth at § 423.100.

- “Part D drug”;

We propose to define “Part D drug” as having the meaning set forth at § 423.100.

- “Primary manufacturer”;

We propose to define “primary manufacturer” as having the meaning given such term pursuant to applicable regulations and guidance for the Medicare Drug Price Negotiation Program.

- “Specified drug”;

We propose to define “specified drug” as meaning, with respect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified manufacturer.

- “Specified small manufacturer drug”;

We propose to define “specified small manufacturer drug” as meaning, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified small manufacturer.

- “Total expenditures”.

We propose to define “total expenditures” as meaning, with respect

to Part D, the total gross covered prescription drug costs, as defined in § 423.308; and as meaning, with respect to Part B, the total Medicare allowed amount (that is, total allowed charges), inclusive of beneficiary cost sharing, for Part B drugs and biologicals, except that expenditures for a drug or biological that are bundled or packaged into the payment for another service are excluded.

4. Conditions for Coverage of Drugs Under Part D (§ 423.2708)

Section 1860D–43(a) of the Act, as amended by the IRA, specifies that, beginning January 1, 2025, in order for Part D coverage to be available for the covered Part D drugs of a manufacturer, the manufacturer must participate in the Manufacturer Discount Program and have entered into and have in effect a Manufacturer Discount Program agreement with CMS, as described in section 1860D–14C(b) of the Act. Operationally, coverage of a drug under a Manufacturer Discount Program agreement is determined by coverage of its labeler code (as defined at § 423.100) under such agreement. As discussed in section 40 of the Manufacturer Discount Program Final Guidance, CMS maintains a list of all labeler codes that are covered by a Manufacturer Discount Program agreement, which is updated monthly and posted on the CMS website to assist Part D sponsors in accurately adjudicating claims at the point of sale. As described in more detail in section II.C.12. of this preamble, manufacturers are required to provide CMS with a complete list of the labeler codes covered under their agreements.

Any Part D drug that is a selected drug during a price applicability period with respect to such drug, is excluded from the definition of applicable drug under section 1860D–14C(g)(2)(B) of the Act and, therefore, not subject to applicable discounts under the Manufacturer Discount Program when dispensed during a price applicability period. However, a selected drug would otherwise meet the definition of an applicable drug, but for it being in a price applicability period following its selection into the Medicare Drug Price Negotiation Program. Therefore, applying section 1860D–43(a) of the Act’s coverage exclusion in the absence of a Manufacturer Discount Program agreement to both applicable drugs and selected drugs provides incentive for manufacturers of brand name drugs and biological products to participate in the Manufacturer Discount Program, while not undermining beneficiary access to generics. Moreover, this interpretation is consistent with the IRA’s addition of

section 1860D–43(c)(2) of the Act, which prohibits the Secretary from authorizing coverage for a covered Part D drug of a manufacturer without a Manufacturer Discount Program agreement for any period described in section 5000D(c)(1) of the Internal Revenue Code under the exception for drugs determined to be essential to the health of Part D enrollees. This provision further demonstrates that the statute does not allow for a selected drug to be eligible for Part D coverage in the absence of a Manufacturer Discount Program agreement. As stated in section 40 of the Manufacturer Discount Program Final Guidance and consistent with the policy on applicable drugs, beginning January 1, 2025, Part D coverage for selected drugs during a price applicability period is available only for selected drugs for which the labeler code is covered by a Manufacturer Discount Program agreement with CMS, as described in section 1860D–14C(b) of the Act.

Accordingly, at § 423.2708(a), we propose to codify that, in order for coverage to be available under Part D for a Part D drug of a manufacturer that is an applicable drug or a selected drug during a price applicability period:

- The FDA-assigned labeler code of such drug must be covered under a Manufacturer Discount Program agreement that is in effect;
- The manufacturer must participate in the Manufacturer Discount Program; and
- The manufacturer must have entered into and have in effect a Manufacturer Discount Program agreement.

We expect each manufacturer choosing to participate in the Manufacturer Discount Program to enter into its own Manufacturer Discount Program agreement with CMS. However, we acknowledge a longstanding practice where CMS has permitted manufacturers to cover by their Manufacturer Discount Program agreement (and previously by their Coverage Gap Discount Program agreement) labeler code(s) assigned by the FDA to another manufacturer. CMS does not currently and is not proposing to prohibit this practice, provided all other requirements as discussed in this proposed rule are met. As such, we clarify that a manufacturer is considered to participate in the Manufacturer Discount Program and to have entered into and have in effect a Manufacturer Discount Program agreement under proposed § 423.2708(a)—and thus, under section 1860D–43(a) of the Act—if such manufacturer executes and has in effect its own Manufacturer Discount

Program agreement or participates by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement that is in effect. We propose to codify this requirement at § 423.2708(b).

We further clarify that, while a manufacturer that participates in the Manufacturer Discount Program in accordance with proposed § 423.2708(b)(2) is a participating manufacturer, as described in more detail in section II.C.12. of this preamble, only the entity that executes an agreement pursuant to proposed § 423.2708(b)(1) is an agreement holder (as defined at § 423.2704). Consistent with our longstanding practice, only the agreement holder is a party to the Manufacturer Discount Program agreement with CMS, and the agreement holder is the entity subject to the rights and obligations of the Manufacturer Discount Program agreement, including the obligation to pay all invoiced amounts under such agreement.

In accordance with section 1860D–43(c)(1)(A) of the Act, we propose to codify at § 423.2708(c) that an applicable drug of a manufacturer that does not participate in the Manufacturer Discount Program or has not entered into and does not have in effect a Manufacturer Discount Program agreement under section 1860D–14C(b) of the Act is not excluded from Part D coverage if CMS has made a determination that the availability of the applicable drug is essential to the health of Part D enrollees. In addition, we propose to codify that, as specified in section 1860D–43(c)(2) of the Act, this exception to the exclusion from Part D coverage does not apply to any applicable drug or selected drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to such manufacturer.

Consistent with our prior interpretation of section 1860D–43(a) of the Act under the Coverage Gap Discount Program, for purposes of the Manufacturer Discount Program, the exclusion from Part D coverage applies only to applicable drugs and selected drugs not covered by a Manufacturer Discount Program agreement that is fully executed and in effect. Coverage under Medicare Part D is available to non-applicable drugs of a manufacturer regardless of whether the manufacturer participates in the Manufacturer Discount Program or has a Manufacturer Discount Program agreement in effect.

With regard to the Coverage Gap Discount Program, we previously explained our interpretation that the

conditions for coverage described in section 1860D–43(a) of the Act must be read together with section 1860D–14A of the Act's provision for Part D coverage of non-applicable drugs under certain circumstances in the absence of a Coverage Gap Discount Program agreement (77 FR 22082). The IRA adopted parallel language for the Manufacturer Discount Program, including section 1860D–14C(f) of the Act, which states that “[n]othing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).” For the same reasons described in the Manufacturer Discount Program Final Guidance and our prior rulemaking, we propose to adopt the same interpretation here with regard to the parallel provisions of section 1860D–14C of the Act. Accordingly, at § 423.2708(d), we propose that non-applicable drugs, as we propose to define the term in § 423.100, will continue to be coverable under Part D whether or not the manufacturer participates in the Manufacturer Discount Program or has a Manufacturer Discount Program agreement in effect.

5. Applicable Discounts (§ 423.2712)

Under the Manufacturer Discount Program, once an enrollee incurs costs exceeding the annual deductible specified in section 1860D–2(b)(1) of the Act, that is, the deductible under the defined standard benefit, manufacturer discounts are available in both the initial and catastrophic coverage phases of the benefit. The applicable discount lowers Part D sponsor liability on the negotiated price of the drug.

a. Defined

As described in section 50 of the Manufacturer Discount Program Final Guidance, for the purposes of the Manufacturer Discount Program, “applicable discount” means, subject to the phase-ins and the straddle claims policy described in this section, with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary (as we propose to define in § 423.100) who has—

- Not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act for the year, 10 percent of the negotiated price of such drug; and

• Incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act for the year, 20 percent of the negotiated price of such drug.

We propose to codify this policy at § 423.2712(a). Consistent with the statutory requirements and the Manufacturer Discount Program Final Guidance, the applicable discount is not available until the enrollee has incurred costs exceeding the annual deductible specified in section 1860D–2(b)(1) of the Act, regardless of whether the enrollee has to pay a deductible (for example, through eligibility for an income-related subsidy or enrollment in an enhanced benefit plan with a reduced or no deductible, or for a drug that is not subject to the deductible, such as a covered insulin product or an Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccine). Because the applicable discount and enrollee cost sharing are both calculated based on the negotiated price of the drug, as described in section II.A. of this proposed rule, the applicable discount will not affect the application of the standard 25 percent coinsurance under section 1860D–2(b)(2)(A) of the Act or the application of the copayment amount under section 1860D–2(b)(4)(A) of the Act unless, after the discount is applied to the negotiated price of the drug, the enrollee cost sharing specified under the plan would exceed such negotiated price minus the applicable discount. In such a situation, the enrollee cost sharing will be the negotiated price minus the applicable discount. We propose to codify this at § 423.2712(g).

In accordance with section 1860D–14C(c)(1)(C) of the Act, we propose to codify at § 423.2712(b) our policy that the value of the discount is calculated before the application of supplemental benefits, and at § 423.2712(c) that the applicable discount must be calculated before any coverage or financial assistance under another health or prescription drug benefit plan or program that provides prescription drug coverage or financial assistance.

b. Application of Discount Phase-In for Specified Manufacturers and Specified Small Manufacturers

The IRA provides for lower applicable discounts for certain manufacturers' applicable drugs marketed as of August 16, 2022, during a multi-year phase-in period which concludes by 2031. Under section 1860D–14C(g)(4) of the Act,

there are two such phase-ins: one for certain applicable drugs of specified manufacturers dispensed to applicable beneficiaries who are eligible for LIS under section 1860D–14(a) of the Act and one for certain applicable drugs of specified small manufacturers dispensed to all applicable beneficiaries.

The applicable discount paid by specified manufacturers for specified drugs dispensed to applicable beneficiaries who are eligible for LIS, referred to in the statute as the “specified LIS percent,” is defined in section 1860D–14C(g)(4)(B) of the Act. The discount paid by specified small manufacturers for specified drugs dispensed to all applicable beneficiaries, referred to in the statute as the “specified small manufacturer percent,” is defined in section 1860D–14C(g)(4)(C) of the Act. These provisions, which also set forth the criteria by which specified manufacturers and specified small manufacturers are defined, require such manufacturers to pay, when applicable, the phased-in discount.

(1) Applicable LIS Percent

Under section 1860D–14C(g)(4)(B) of the Act, for an applicable drug of a specified manufacturer (as described at proposed § 423.2716(a)) that is marketed as of August 16, 2022, and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3) of the Act), the applicable discount is as follows:

• For such individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- ++ For 2025, 1 percent;
- ++ For 2026, 2 percent;
- ++ For 2027, 5 percent;
- ++ For 2028, 8 percent; and
- ++ For 2029 and each subsequent year, 10 percent.

• For such individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- ++ For 2025, 1 percent;
- ++ For 2026, 2 percent;
- ++ For 2027, 5 percent;
- ++ For 2028, 8 percent;
- ++ For 2029, 10 percent;
- ++ For 2030, 15 percent; and
- ++ For 2031 and each subsequent year, 20 percent.

We propose to codify the policy for the applicable LIS percent at § 423.2712(d)(1).

(2) Applicable Small Manufacturer Percent

Under section 1860D–14C(g)(4)(C) of the Act, for an applicable drug of a

specified small manufacturer (as described at proposed § 423.2716(b)), that is marketed as of August 16, 2022, and dispensed for an applicable beneficiary, the applicable discount is as follows:

• For such individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- ++ For 2025, 1 percent;
- ++ For 2026, 2 percent;
- ++ For 2027, 5 percent;
- ++ For 2028, 8 percent; and
- ++ For 2029 and each subsequent year, 10 percent; and

• For such individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- ++ For 2025, 1 percent;
- ++ For 2026, 2 percent;
- ++ For 2027, 5 percent;
- ++ For 2028, 8 percent;
- ++ For 2029, 10 percent;
- ++ For 2030, 15 percent; and
- ++ For 2031 and each subsequent year, 20 percent.

We propose to codify the policy for the applicable small manufacturer percent at § 423.2712(d)(2).

(3) Marketed as of the Date of Enactment

Sections 1860D–14C(g)(4)(B)(i) and 1860D–14C(g)(4)(C)(i) of the Act limit the application of the discount phase-ins for specified manufacturers and specified small manufacturers, respectively, to drugs of such manufacturers that are “marketed as of the date of enactment” (that is, August 16, 2022). CMS interprets the reference to a drug that is marketed as of August 16, 2022 to refer to a drug that was marketed by the manufacturer on one specific, backward-looking date, that is, the date of enactment of the IRA. Accordingly, for purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers subject to phase-ins, CMS will determine whether an applicable drug had Part D expenditures on or before August 16, 2022, and did not have a marketing end date on the FDA NDC SPL Data Elements File before August 17, 2022.

We propose to codify this requirement at § 423.2712(d)(3).

c. Straddle Claims

In the case of a claim for an applicable drug for an applicable beneficiary that “straddles” multiple phases of the benefit, section 1860D–14C(g)(4)(E) of the Act requires that for claims that do not fall entirely—

• Above the annual deductible specified in section 1860D–2(b)(1) of the

Act, the manufacturer provides the applicable discount on only the portion of the negotiated price that falls above the deductible; and

- Below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act, the manufacturer provides the applicable discount on each portion of the negotiated price in accordance with this section based on the benefit phase into which each portion of the negotiated price falls.

We propose to codify the policy for straddle claims at § 423.2712(e).

d. Claims Not Subject to Discount

Under the Coverage Gap Discount Program, certain coordination of benefits and other non-standard Part D claims for applicable drugs were not subject to manufacturer discounts. In response to the Manufacturer Discount Program Draft Guidance, released on May 12, 2023, we received public comments seeking clarification about how to calculate manufacturer discounts under the Manufacturer Discount Program in certain situations involving coordination of Part D with other benefits and non-standard format claims. In the Manufacturer Discount Program Final Guidance, CMS responded to those comments by clarifying that discounts are not paid on Medicare Secondary Payer (MSP) claims or Medicaid subrogation claims involving an applicable drug.

As described in section 60.1.4 of the Manufacturer Discount Program Final Guidance, discounts are not applied to MSP claims under the Manufacturer Discount Program because CMS is unable to ascertain from the PDE how much liability, if any, the Part D sponsor has on such claims. Discounts are not applied to Medicaid subrogation claims under the Manufacturer Discount Program because drug costs reported on such claims are accounted for during the payment reconciliation process as contributing entirely to Covered D Plan Paid Amounts (CPP). We propose to codify those policies at § 423.2712(f)(1) and (2), respectively.

The Manufacturer Discount Program Final Guidance also referred to Indian Health Service (IHS) “subrogation” claims as not being subject to discounts under the Manufacturer Discount Program. We clarify that, while the guidance specifically referred to IHS claims, our intent was to adopt the longstanding policy applied under the Coverage Gap Discount Program where coordination of benefits claims involving payer-to-payer reconciliation are not subject to manufacturer discounts. Using an example from

Appendix E, Chapter 14, of the Medicare Prescription Drug Benefit Manual, if a tribal member newly enrolled in Part D is initially unable to access their Part D benefits through their Part D plan, the tribe may step in to pay for the individual’s Part D drugs. In this scenario, the tribe is entitled to seek compensation from the Part D plan once enrollment is confirmed. Consistent with CMS coordination of benefits requirements at § 423.464, the Part D plan is required to reimburse the tribe when the tribe has paid primary. In accordance with these requirements, we propose at § 423.2712(f)(3) to specify that non-standard format coordination of benefits claims involving an applicable drug are not subject to discounts under the Manufacturer Discount Program. We further clarify that claims submitted by a pharmacy operated by IHS, tribes or tribal organizations, or Urban Indian organizations to a Part D plan as the primary payer for an applicable drug dispensed to an applicable beneficiary are subject to discounts under the Manufacturer Discount Program, consistent with our policy under the Coverage Gap Discount Program.

Lastly, at § 423.2712(f)(4) we propose to codify our longstanding policy that manual claims involving an applicable drug with a service provider identification qualifier of “Other” are not subject to discounts under the Manufacturer Discount Program. Because PDE records for such claims do not have a service provider identifier, there is no way to furnish the manufacturer with an invoice containing all of the required data elements necessary for manufacturer review to confirm or dispute the validity of the dispensing entity. Section II.C.13.a. of this preamble contains a more detailed discussion of the required data elements for manufacturer invoices.

As discussed in section II.C.3. of this preamble, compounded drug products are excluded from the definition of applicable drug that we propose to revise at § 423.100; as such, claims for Part D compounds are not subject to discounts under the Manufacturer Discount Program.

6. Phase-In of Applicable Discounts (§§ 423.2716 Through 423.2728)

As discussed in sections 50.1.1 and 50.1.2 of the Manufacturer Discount Program Final Guidance, the IRA establishes lower percentages for discounts on applicable drugs that are subject to phase-ins for specified manufacturers and specified small manufacturers. Since the discount

reduces the plan liability for applicable drugs, Part D sponsors are responsible for covering the remaining amount of the negotiated price, less enrollee cost sharing, for applicable drugs subject to a phased-in discount percentage as discussed in this section. For example, the applicable discount for applicable drugs in the initial coverage phase is 10 percent. In 2025, the applicable LIS percent for a specified drug dispensed to an LIS enrollee during the initial coverage phase is 1 percent. In a defined standard plan, the plan liability in the initial coverage phase is 75 percent of the negotiated price before the discount. With a 10 percent applicable discount, the plan liability would be reduced to 65 percent of the negotiated price. With a 1 percent applicable LIS percent in 2025, the plan liability would be reduced to 74 percent of the negotiated price.

Section 1860D–14C(b)(1)(A) of the Act specifies that a Manufacturer Discount Program agreement shall require the agreement holder to provide discounted prices for applicable drugs covered by its agreement when dispensed to applicable beneficiaries. The IRA does not provide a mechanism by which CMS could permit specified manufacturers or specified small manufacturers to “opt out” of the phase-in discounts. At § 423.2716, we propose to codify, without modification, the criteria for phase-in eligibility for specified manufacturers and specified small manufacturers established in the Manufacturer Discount Program Final Guidance.

a. Specified Manufacturer

Pursuant to section 1860D–14C(g)(4)(B)(ii) of the Act, a specified manufacturer is a manufacturer of an applicable drug that, in 2021 had—

- A Coverage Gap Discount Program agreement in effect;¹⁹
- Total expenditures for all of its specified drugs (as proposed at § 423.2704) covered by a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 represented less than 1.0 percent of total expenditures for all Part D drugs in 2021; and
- Total expenditures for all of its specified drugs that are single source

¹⁹ A manufacturer that participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) were listed on another manufacturer’s Coverage Gap Discount Program agreement would be considered to have had an agreement in effect during 2021. See November 17, 2023 HPMS memorandum entitled, “Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers” for more information.

drugs and biological products for which payment may be made under Part B in 2021 represented less than 1.0 percent of the total expenditures under Part B for all drugs or biological products in 2021.

Pursuant to the aggregation rule set forth in section 1860D–14C(g)(4)(B)(ii)(II)(bb) of the Act, all entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section. Our proposed definition of specified manufacturer is subject to the limitation with respect to manufacturer acquisitions proposed at § 423.2724 and discussed in section II.C.6.d. of this preamble.

The eligibility criteria for specified manufacturers are proposed at § 423.2716(a) and the aggregation rule is proposed at § 423.2716(c).

b. Specified Small Manufacturer

Pursuant to section 1860D–14C(g)(4)(C)(ii) of the Act, a specified small manufacturer is a manufacturer of an applicable drug that, in 2021—

- Is a specified manufacturer as described at proposed § 423.2716(a); and
- The total expenditures under Part D for any one of its specified small manufacturer drugs (as defined in § 423.2704) covered under a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 are equal to or greater than 80 percent of the total expenditures for all its specified small manufacturer drugs covered under Part D in 2021.

Pursuant to the aggregation rule set forth in section 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act, all entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section. Our proposed definition of specified small manufacturer is subject to the limitation with respect to manufacturer acquisitions proposed at § 423.2724 and discussed in section II.C.6.d. of this preamble.

The eligibility criteria for specified small manufacturers are proposed at § 423.2716(b) and the aggregation rule is proposed at § 423.2716(c).

c. Determination of Phase-In Eligibility

As discussed in section 50.1 of the Manufacturer Discount Program Final Guidance, CMS identifies which

manufacturers qualify for phase-ins by analyzing Medicare Part B claims data, Part D PDE data, and ownership information submitted by manufacturers. All manufacturers that sign a Manufacturer Discount Program agreement that takes effect prior to the end of the phase-in periods will be considered and do not need to submit a separate application. Our policy describing the methodology used to identify manufacturers eligible for phase-ins was provided in the November 17, 2023 HPMS memorandum titled “Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers” (Manufacturer Discount Program Methodology).

The phase-in determination is a one-time assessment that CMS performs with respect to each manufacturer when it executes a Manufacturer Discount Agreement or when a manufacturer’s labeler code(s) is first added to another manufacturer’s Manufacturer Discount Program agreement. As such, the phase-in statuses have already been determined for likely the vast majority of manufacturers that will participate in the Manufacturer Discount Program during the phase-in periods (that is, through 2030). Codifying the methodology described in the Manufacturer Discount Program Methodology for identifying specified manufacturers and specified small manufacturers ensures consistency across the program by applying the same methodology to future cases of new phase-in determinations to be made under the regulations proposed in this rule (for example, when a new manufacturer enters into a Manufacturer Discount Program agreement with respect to 2027 or thereafter) as the methodology that was applied to the manufacturers currently participating in the Manufacturer Discount Program. We are proposing to codify such methodology at § 423.2720.

Specifically, we propose to codify at § 423.2720 that for each manufacturer with one or more FDA-assigned labeler codes covered by a Manufacturer Discount Program agreement, CMS will determine whether the manufacturer is a specified manufacturer or a specified small manufacturer when the manufacturer executes a Manufacturer Discount Program agreement, or, in the case of a manufacturer whose FDA-assigned labeler code(s) is covered by another manufacturer’s Manufacturer Discount Program agreement, when such labeler code(s) is first added to such agreement. In addition, we propose to codify that in applying the

aggregation rule at § 423.2716(c), CMS will attribute expenditures for a drug to a manufacturer based on the NDC(s) for the drug, as reported on PDE records. Specifically, CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer to whom the labeler code is assigned by the FDA.

As discussed in detail later in this section, we propose at paragraph (a) of § 423.2720 the methodology for identifying “specified manufacturers”, at paragraph (b) of § 423.2720 the methodology for identifying “specified small manufacturers”, and at paragraph (c) the approach CMS will use to issue the phase-in determination notices once a phase-in determination is made.

For identification of a specified manufacturer, we propose to codify at § 423.2720(a)(1) that a manufacturer is considered to have had a Coverage Gap Discount Program agreement in 2021, as specified at § 423.2716(a)(1), if the manufacturer (i) had a Coverage Gap Discount Program agreement in effect during 2021, or (ii) participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) was covered by another manufacturer’s Coverage Gap Discount Program agreement in effect during 2021.

As described in the Manufacturer Discount Program Methodology, CMS will calculate the three values needed for determining which manufacturers that had a Coverage Gap Discount Program agreement in 2021 are specified manufacturers and specified small manufacturers. The three values are:

- The manufacturer’s percent share of Part D total expenditures,
- The manufacturer’s percent share of Part B total expenditures, and
- Each drug’s percent share of the specified manufacturer’s Part D total expenditures.

The first value that needs to be determined is each manufacturer’s share of Part D total expenditures, which will be used to determine if the manufacturer’s total expenditures for all of its applicable drugs covered under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, represented less than 1.0 percent of total expenditures for all Part D drugs in 2021. CMS will identify manufacturers that meet this threshold for the specified manufacturer phase-in by first summing the 2021 Part D total expenditures for Part D drugs, then summing the 2021 Part D total expenditures for applicable drugs for each manufacturer, and finally, identifying each manufacturer for which 2021 Part D total expenditures for applicable drugs are less than 1.0

percent of all 2021 Part D total expenditures.

The first step is to calculate the Part D total expenditures for 2021. We will calculate the Part D total expenditures for 2021 reported on all final action,²⁰ non-delete Prescription Drug Event (PDE) records submitted as of June 30, 2022, which represents the annual PDE data submission deadline for Part D payment reconciliation, for all Part D drugs dispensed in benefit year 2021. This value represents the Part D total expenditures and will be used as the denominator when calculating the percent share of Part D total expenditures attributable to each manufacturer's applicable drugs in step 3 below.

The second step is to calculate each manufacturer's Part D total expenditures for applicable drugs for 2021. For purposes of calculating each manufacturer's Part D total expenditures for applicable drugs, CMS will identify the National Drug Codes (NDCs) attributable to the manufacturer that have a Marketing Category Code of 'NDA', 'BLA', or 'NDA AUTHORIZED GENERIC' on the NDC SPL Data Elements (NSDE) File maintained by the Food and Drug Administration (FDA). CMS will attribute an NDC as reported on the PDE record to the manufacturer using the labeler code extracted from the first 5 digits of each NDC. CMS will calculate the Part D total expenditures for each relevant NDC attributable to the manufacturer as reported on all final action, non-delete PDE records submitted as of June 30, 2022 for applicable drugs dispensed in benefit year 2021. CMS will then sum the Part D total expenditures for all relevant NDCs attributable to the manufacturer—that is, the Part D total expenditures for all applicable drugs of all manufacturers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, as identified by the ownership information submitted and attested to by the manufacturer (as described in the aggregation rule proposed at § 423.2716(c)).

The third step is to calculate each manufacturer's percent share of Part D total expenditures for 2021. CMS will divide the Part D total expenditures for applicable drugs of the manufacturer,

determined in step 2 above, by the Part D total expenditures for all Part D drugs, determined in step 1 above, and then multiply by 100 to get the manufacturer's percent share. If a manufacturer's Part D total expenditures for its applicable drugs are less than 1.0 percent of the 2021 Part D total expenditures, CMS will consider the manufacturer to have satisfied the Part D total expenditure criterion for specified manufacturer phase-in eligibility.

We propose to codify this part of the methodology at § 423.2720(a)(2).

The next value that needs to be determined is each manufacturer's share of Part B total expenditures, which will be used to determine if the manufacturer's total expenditures for all of its specified drugs that are single source drugs or biological products represented less than 1.0 percent of the total expenditures for all drugs or biologicals under Part B in 2021, excluding expenditures for a drug or biological that are bundled or packaged into payment for another service. This calculation involves three steps: identifying 2021 Part B total expenditures for drugs and biological products, identifying the 2021 Part B total expenditures for single-source drugs and biological products for each manufacturer that had a Coverage Gap Discount Program agreement(s) in 2021, and identifying eligible manufacturers for which Part B total expenditures for single source drugs or biological products represent less than 1.0 percent of total expenditures for drug and biological products under Part B for 2021.

The first step is to calculate Part B total expenditures for all drugs and biological products for 2021. CMS will identify all Healthcare Common Procedure Coding System (HCPCS) codes for drugs and biological products. Then, CMS will calculate Part B Carrier, durable medical equipment (DME), and Outpatient Medicare Part B total expenditures for drug and biological products for Fee-for-Service claim line items with a drug- or biological product-related HCPCS code, submitted as of December 31, 2022, which represents the Medicare Fee-For-Service submission deadline for CY 2021.

The second step is to calculate each manufacturer's Part B total expenditures for applicable drugs that are single-source drugs and biological products for 2021. CMS will first map the HCPCS codes identified in step 1 above to NDCs using the NDC–HCPCS Crosswalk file provided as part of the CMS ASP Pricing File and the Pricing, Data Analysis and Coding (PDAC) HCPCS to

NDC crosswalk file. Since the ASP NDC–HCPCS Crosswalk file is not a comprehensive list of all drugs/NDCs available in the United States, a Medi-Span Generic Product Identifier (GPI–14) expansion is used to help identify all NDCs associated with the HCPCS codes. We define a single source drug or biological following the definition in section 1847A(c)(6)(D) of the Act and we are identifying NDCs for single source drugs using Medi-Span and the FDA NSDE marketing category data, or biological products using the FDA Purple Book. A HCPCS code is considered to be indicative of a single source drug or biological product if each NDC associated with the HCPCS code is for a single source drug or biological product. The corresponding NDCs are used to determine the labeler codes for each applicable HCPCS code. CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer. Since a HCPCS code can be mapped to multiple NDCs and labeler codes, it can also be associated with multiple manufacturers. While Part B single source drugs or biological products can be mapped to a particular HCPCS code, mapping applicable Part B expenditures to a particular manufacturer when a particular HCPCS code may reflect drugs of multiple manufacturers can be challenging. For this reason, CMS will only count the payments associated with a HCPCS code toward a manufacturer's 2021 Part B total expenditures if the HCPCS code is only mapped to drugs of that same manufacturer, consistent with the aggregation rule proposed at § 423.2716(c).

The third step is to calculate each manufacturer's percent share of Part B total expenditures for 2021. CMS will divide the Part B total expenditures for the applicable drugs that are single source drugs and biological products of the manufacturer, determined in step 2 above, by the Part B total expenditures for all drugs and biological products, determined in step 1 above, and then multiply by 100 to get the manufacturer's percent share. If a manufacturer's Part B total expenditures are less than 1.0 percent of the 2021 Part B total expenditures, CMS will consider the manufacturer to have satisfied the Part B total expenditure criterion for the specified manufacturer phase-in eligibility.

We propose to codify this part of the methodology at § 423.2720(a)(3).

The last value that needs to be determined for each specified manufacturer is the total expenditures under Part D for any one of the manufacturer's specified drugs covered

²⁰ CMS uses the term "final action" to describe the most recently accepted original, adjustment, or delete PDE record representing a single dispensing event. See the 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, page 3–29, available at [https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1-Prescription%20Drug%20Program%20\(Part%20D\)-Training](https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1-Prescription%20Drug%20Program%20(Part%20D)-Training).

under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, which will be used to determine if the manufacturer's total expenditures for one specified drug are equal to or greater than 80 percent of the total expenditures for all of its specified drugs covered under Part D in 2021 such that the manufacturer is eligible for the specified small manufacturer phase-in.

The first step is to aggregate all NDCs for applicable drugs reported on PDEs for each specified manufacturer that have the same active moiety for drug products, or same active ingredient for biological products, and with the same holder of the NDA or BLA. To determine one drug's share of a manufacturer's Part D total expenditures, which we will use to identify specified small manufacturers, we first note that for drug products, one specified small manufacturer drug will include all dosage forms and strengths of a drug with the same active moiety and the same holder of the NDA,²¹ inclusive of products that are marketed pursuant to different NDAs. For biological products, one specified small manufacturer drug will include all dosage forms and strengths of the biological product with the same active ingredient and the same holder of the BLA,²² inclusive of products that are marketed pursuant to different BLAs. CMS will identify the holder of the NDA/BLA for a drug or biological product as reported in Drugs@FDA or FDA Purple Book. If a drug is a fixed combination drug²³ with two or more active moieties/active ingredients, the distinct combination of active moieties/active ingredients will be considered as one active moiety/active ingredient for the purpose of identifying a specified small manufacturer drug. Therefore, all formulations of this distinct combination with the same NDA/BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties/active ingredients with the same NDA/BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate specified small manufacturer drug. CMS will attribute Part D expenditures for a drug, including authorized generic drugs and repackaged and relabeled drugs, to a specified manufacturer based on the NDC(s) for the drug, as reported on PDE records. Specifically, CMS will match

the labeler code extracted from the first 5 digits of each NDC to the manufacturer. (See the aggregation rule proposed at § 423.2716(c)).

The second step is to calculate the Part D total expenditures for each aggregated drug for 2021. CMS will calculate the Part D total expenditures for each aggregated drug attributable to the manufacturer as identified in step 1 by summing the Part D total expenditures for all NDCs under each aggregated drug as reported on all final action, non-delete PDE records submitted as of June 30, 2022, for drugs dispensed in benefit year 2021.

The third step is to calculate each drug's percent share of the specified manufacturer's Part D total expenditures for applicable drugs for 2021. CMS will divide the Part D total expenditures for each aggregated drug, determined in step 2, by the Part D total expenditures for all applicable drugs of the specified manufacturer, and then multiply by 100 to get the percent share. Specified manufacturers that have 2021 Part D total expenditures for a single specified drug that are equal to or greater than 80 percent of the specified manufacturer's Part D total expenditures for all specified drugs are considered to have met the eligibility criteria for specified small manufacturers and are eligible for the specified small manufacturer phase-in.

We propose to codify this part of the methodology at § 423.2720(b).

Finally, at paragraph (c)(1) of § 423.2720, we propose to specify that CMS will issue a phase-in determination notice to each manufacturer that has executed and has in effect a Manufacturer Discount Program agreement when such determination is made, delivered by electronic mail, to the primary point of contact as identified by the manufacturer. At paragraph (c)(2) of § 423.2720, we propose to specify that in the case of a manufacturer that participates in the Manufacturer Discount Program by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement, CMS will issue a phase-in eligibility determination notice to the agreement holder.

For purposes of identifying manufacturers eligible for phase-ins, the aggregation rule at section 1860D–14C(g)(4)(B)(ii)(II)(bb) of the Act for specified manufacturers and section 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act for specified small manufacturers requires that CMS treat as a single manufacturer all entities that are treated as a single employer under subsection

(a) or (b) of section 52 of the Internal Revenue Code of 1986. As noted previously, we propose to codify the aggregation rule at § 423.2716(c). The statute, at section 1860D–14C(g)(4)(B)(ii)(II)(bb) of the Act for specified manufacturers and section 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act for specified small manufacturers, also requires that manufacturers provide and attest to necessary information as specified by CMS. Because CMS does not have information about which entities are treated as a single employer under the Internal Revenue Code of 1986, manufacturers that wish to participate in the Manufacturer Discount Program must submit and attest to information about the company and its products in order for CMS to make a determination about phase-in eligibility.

d. Effect of Manufacturer Acquisition on Phase-In Eligibility

Section 1860D–14C(g)(4)(B)(ii)(III) of the Act requires that when a specified manufacturer is acquired after 2021 by another manufacturer that is not a specified manufacturer, the acquired manufacturer is no longer a specified manufacturer effective at the beginning of the plan year immediately following the acquisition. For acquisitions before 2025, the change is effective January 1, 2025. Section 1860D–14C(g)(4)(C)(ii)(III) of the Act establishes a similar requirement for specified small manufacturers: when acquired after 2021 by a manufacturer that is not a specified small manufacturer, such manufacturer is no longer a specified small manufacturer effective at the beginning of the plan year immediately following the acquisition (or January 1, 2025, for acquisitions before 2025).

While the statute is explicit that an acquired specified manufacturer or specified small manufacturer loses that specific phase-in status upon acquisition by another manufacturer that is not a specified manufacturer or a specified small manufacturer, respectively, it does not expressly address whether such acquired manufacturers assume the phase-in eligibility of the acquiring manufacturer or lose all phase-in eligibility (for example, a specified manufacturer is acquired by a specified small manufacturer or a specified small manufacturer is acquired by a specified manufacturer). Similarly, the statute does not expressly address what happens if a specified manufacturer or a specified small manufacturer acquires a manufacturer that CMS determined was not eligible for either phase-in. Consistent with our approach to

²¹ As described in section 505(c) of the FD&C Act.

²² As described in section 351(a) of the PHS Act.

²³ As described in 21 CFR 300.50.

acquisitions under the Manufacturer Discount Program thus far, we propose at § 423.2724 to review phase-in status bidirectionally such that acquired manufacturers may gain or lose phase-in eligibility as the result of an acquisition. In other words, regardless of the phase-in status of the acquiring manufacturer or the acquired manufacturer at the time of the acquisition, when a manufacturer acquires another manufacturer (that is, the acquired manufacturer becomes part of such acquiring manufacturer under the aggregation rule at § 423.2716(c)), the acquired manufacturer will assume the phase-in status of the acquiring manufacturer, as of the effective date following the acquisition discussed later in this section. CMS believes this bidirectional policy best aligns with the statutory structure and purpose of the phase-ins. First, we believe this policy is most consistent with the directive in sections 1860D–14C(g)(4)(B)(ii)(II)(bb) and 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act to treat all entities, including corporations, partnerships, proprietorships, and other entities, treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 as one manufacturer for the purposes of the phase-ins. Without applying the effect of acquisitions bidirectionally, manufacturers that are members of the same controlled group could have different phase-in eligibility statuses as a result of an acquisition. Additionally, while a specified small manufacturer that is acquired by a specified manufacturer will lose its specified small manufacturer status consistent with section 1860D–14C(g)(4)(C)(ii)(III) of the Act, such manufacturer becomes a specified manufacturer under this policy, rather than losing eligibility for phase-in altogether.

We propose that all changes to a manufacturer's phase-in status as a result of an acquisition will become effective on January 1 of the year following the acquisition or, in the case of an acquisition before 2025, effective January 1, 2025. This aligns the effective date of changes to a manufacturer's phase-in status across all acquisitions with the requirements in sections 1860D–14C(g)(4)(B)(ii)(III) and 1860D–14C(g)(4)(C)(ii)(III) of the Act discussed previously and is consistent with our approach to date for acquisitions that have already occurred. Operationally, adopting a January 1 effective date minimizes burden on Part D sponsors who would otherwise need to regularly make additional claims processing changes to accommodate phase-in status

changes throughout the year given the frequency of corporate ownership changes in the pharmaceutical industry. It also minimizes any need for Part D sponsors to make retrospective PDE adjustments if, for example, CMS does not become aware of the acquisition until after it occurs.

In sum, in alignment with the statutory requirements and the procedures already in place under the Manufacturer Discount Program, we propose at § 423.2724 to codify a regulatory policy for manufacturer acquisitions where, regardless of the manufacturer's phase-in eligibility status prior to the acquisition, once acquired, the acquired manufacturer is recognized as having the phase-in eligibility status of the acquiring manufacturer. Consistent with the statutory requirements related to the loss of phase-in eligibility, and to minimize any potential impact on Part D sponsors or manufacturers as a result of changes to manufacturer phase-in status in the middle of a plan year, we also propose at § 423.2724 that any change in phase-in eligibility status as a result of an acquisition, regardless of whether the acquired manufacturer gains or loses phase-in eligibility, would be effective on January 1 of the year following the acquisition.

e. Recalculation

We propose to codify the recalculation policy discussed in section 50.2.2 of the Manufacturer Discount Program Final Guidance, with certain modifications, at § 423.2728.

As discussed in the guidance, while the requirements to qualify as a specified manufacturer or specified small manufacturer are set forth in statute, we recognize that, while unlikely, a manufacturer may wish to raise concerns with the outcome of the application of those statutory requirements. As such, CMS established a mechanism for manufacturers that wish to request a recalculation of their phase-in eligibility determination. Such requests can only be filed by the manufacturer that received the determination. We propose to codify this requirement at § 423.2728(a).

Under the recalculation policy, a manufacturer that seeks a recalculation of their phase-in eligibility determination must file the request with CMS no later than 30 calendar days from the date the eligibility determination is electronically sent to the manufacturer. The request must clearly describe the issue(s) forming the basis of the request for recalculation, and include any relevant supporting

information. We propose to codify these requirements at § 423.2728(b).

After consideration of the issues raised in a recalculation request, CMS will decide whether to perform the recalculation, and will issue a written decision to the manufacturer that will include CMS's decision about whether to perform the requested recalculation and, if such recalculation is performed, the resulting eligibility determination. The decision is final and binding, subject to the requirements of the Manufacturer Discount Program under section 1860D–14C of the Act and the Manufacturer Discount Program agreement. We propose to codify this policy at § 423.2728(c).

Finally, at § 423.2728(d), we propose to limit the recalculation process to requests that meet the requirements proposed in § 423.2728(a) and (b). The recalculation request process cannot be used to request or be granted an exception to the requirements set forth in statute that determine eligibility for the specified manufacturer or specified small manufacturer phase-in.

7. Use of a Third Party Administrator (§ 423.2732)

Unlike under the statute establishing the Coverage Gap Discount Program, section 1860D–14C of the Act does not require CMS to engage a third party administrator (TPA) under the Manufacturer Discount Program. However, section 1860D–14C(d)(2) of the Act prohibits CMS from receiving or distributing any funds of a manufacturer under the Manufacturer Discount Program. Because of this limitation, under our authority at section 1860D–14C(d)(1) of the Act, CMS has engaged a TPA to assist in the administration of the Manufacturer Discount Program, which includes, but is not limited to Manufacturer Discount Program invoicing, the receipt and distribution of funds of a manufacturer, and dispute resolution. We propose to codify the agency's engagement of a TPA at § 423.2732(a).

As proposed at § 423.2752(a)(6), the Manufacturer Discount Program agreement requires agreement holders to enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA. It further requires agreement holders to comply with the TPA's instructions, processes, and requirements. We believe these requirements are important because of the quantity of Part D sponsor and manufacturer data elements, and the sensitivity of such data elements, that is processed each quarter by the TPA. Accordingly, we are proposing to codify at § 423.2732(b)(1) that agreement

holders must enter into and have in effect an agreement with the TPA and that such TPA agreement will only terminate upon the termination of the agreement holder's Manufacturer Discount Program agreement.

We are also proposing at § 423.2732(b)(2) that agreement holders must establish and maintain electronic connectivity with the TPA for the purpose of timely transmission of data and funds. Because Part D sponsors, under § 423.505(b)(25), must agree to maintain administrative and management capabilities sufficient for financial, communication, and other activities related to the delivery of Part D services, we have not proposed a separate requirement in subpart AA regarding Part D sponsors' establishment and maintenance of an account on the TPA's electronic portal; we believe § 423.505(b)(25) already establishes this obligation.

8. Requirement for Point-of-Sale Discounts (§§ 423.505 and 423.2736)

a. Point-of-Sale Discounts

Under section 60.1 of the Manufacturer Discount Program Final Guidance, Part D sponsors must provide applicable discounts on applicable drugs at the point of sale on behalf of the manufacturer. This policy aligns with the process used under the Coverage Gap Discount Program since 2011, to which interested parties are accustomed, coupled with prospective payments to sponsors and the payment reconciliation process at proposed § 423.2744(a) and (c), respectively, minimizes burden on plan sponsors, manufacturers, pharmacies, and Part D enrollees. We propose to codify this policy at § 423.2736(a).

In order to provide point-of-sale discounts, plan sponsors must determine whether an enrollee is an applicable beneficiary (as defined at § 423.100), including where the enrollee falls in the phases of the Part D benefit based on their gross drug spend and incurred costs at the time an applicable drug is dispensed; whether a drug is an applicable drug (as defined at § 423.100); and the amount of the discount (in accordance with proposed § 423.2712).

Part D regulations at part 423 subpart K set forth the requirements for Part D contracts between Part D sponsors and CMS. We propose a conforming change to revise the text of § 423.505(b)(24) to specify that Part D sponsors must provide applicable discounts on applicable drugs when dispensed to applicable beneficiaries in accordance with the requirements in subpart W of

part 423 for the Coverage Gap Discount Program and the requirements in subpart AA of part 423 for the Manufacturer Discount Program.

b. Direct Member Reimbursement

As established under section 60.1.1 of the Manufacturer Discount Program Final Guidance, Part D sponsors must provide applicable discounts on claims for applicable drugs submitted by applicable beneficiaries as direct member reimbursements (DMRs), including out-of-network and in-network paper claims, if such claims are payable under the Part D plan. While the sponsor must account for the discount in adjudicating the DMR request and the associated PDE submitted to CMS, the point-of-sale requirement does not apply. We propose codifying this policy at § 423.2736(b). For purposes of discounting DMR claims for prescriptions filled at out-of-network pharmacies, the negotiated price means the plan allowance as set forth in § 423.124. CMS guidance related to DMR processing can be found in Chapter 14, section 50.4.3, of the Medicare Prescription Drug Benefit Manual.²⁴

c. Pharmacy Prompt Payment

Pursuant to section 1860D–14C(c)(1)(B) of the Act, and consistent with section 60.3 of the Manufacturer Discount Program Final Guidance and CMS pharmacy prompt payment requirements at § 423.520, we propose at § 423.2736(c) that Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days (as defined in § 423.100) after the date of dispensing (as defined in § 423.100) of an applicable drug. As described in the definition of date of dispensing, for long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

d. Prescription Drug Event Requirements

We propose codifying at § 423.2736(d) PDE requirements established in section 60.2 of the Manufacturer Discount Program Final Guidance, specifically, that Part D sponsors must report the applicable discounts made available to their enrollees under the Manufacturer Discount Program on the PDE records associated with such discounts. This

information will be used for the cost-based reconciliation of prospective Manufacturer Discount Program payments made to each sponsor (as proposed at § 423.2744(c)) and to invoice agreement holders for reimbursement of the amount advanced on their behalf by the Part D sponsor at the point of sale (as proposed at § 423.2756(a)).

e. Retroactive Adjustments

Under section 60.1.5 of the Manufacturer Discount Program Final Guidance, Part D sponsors must make retroactive adjustments to applicable discounts as necessary to reflect applicable changes, including changes to the claim, beneficiary eligibility, or benefit phase determined after the date of dispensing. We propose codifying this policy at § 423.2736(e).

9. Negative Invoice Payment Process for Part D Sponsors (§ 423.2740)

In certain instances in the quarterly Manufacturer Discount Program invoicing process (proposed at § 423.2756(a)) a Part D sponsor may receive a negative invoice amount. This can occur when a PDE, which had been previously invoiced, is either deleted or adjusted by the plan such that the reported discount amount is less than originally invoiced. A negative invoice amount can be thought of as the amount an agreement holder has overpaid a Part D sponsor in a prior quarter that is now due back to the agreement holder because of a PDE adjustment or deletion. Negative invoice amounts occurred under the Coverage Gap Discount Program, and CMS developed our proposed Manufacturer Discount Program negative invoice policy based on program instruction for the Coverage Gap Discount Program, including the July 12, 2013 HPMS memorandum titled "Instructions for Resolving Coverage Gap Discount Program (CGDP) Negative Invoice Amounts." Accordingly, we propose that Part D sponsors must pay such negative invoices in the manner specified by CMS within 38 calendar days of receipt of the invoice, the same timeframe specified in the July 12, 2013 memorandum. A sponsor's failure to pay such a negative invoice within the 38-day deadline may result in CMS taking compliance action in accordance with § 423.505(n). We propose codifying this negative invoice policy at § 423.2740.

10. Prospective Payments to Part D Sponsors (§ 423.2744)

a. General Rule

We propose at § 423.2744(a) to provide monthly prospective

²⁴ Available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-14-2018.pdf>.

Manufacturer Discount Program payments to Part D sponsors for discounts to advance applicable discounts at the point of sale under proposed § 423.2736(a) and reimburse network pharmacies within the timeframe required under proposed § 423.2736(c).

Consistent with section 60.4 of the Manufacturer Discount Program Final Guidance, CMS calculates Manufacturer Discount Program prospective payments based on the projections in each plan's bid and current enrollment. Under this process, CMS estimates the per member per month cost of the manufacturer discounts for each plan based on a percentage of the cost assumptions submitted with plan bids under § 423.265 and negotiated and approved under § 423.272, adjusted as necessary to account for applicable drug costs for applicable beneficiaries. CMS then multiplies the plan's manufacturer discount estimate by the number of beneficiaries enrolled in the plan and distributes the prospective Manufacturer Discount Program payments to plans on the first of each month. The Manufacturer Discount Program payments are reflected as a separate line item on each plan's Monthly Membership Detail Reports and included in the Part D payments displayed on the Monthly Membership Summary Reports.

When manufacturers pay their quarterly Manufacturer Discount Program invoices, sponsors will appear to have a temporary duplicate payment from two sources, the manufacturer and CMS, for the same expense. After receiving payment from the manufacturer, the Part D sponsor no longer needs the cash flow advance from the prospective Manufacturer Discount Program payment. Therefore, CMS will offset the monthly prospective Manufacturer Discount Program payment, with the offset amount being equal to the total manufacturer discount amount received by the Part D sponsor from the manufacturer in the previous quarter.

b. Exception

As described in section 60.4 of the Manufacturer Discount Program Final Guidance, employer group waiver plans (EGWPs) do not submit Part D bids; therefore, CMS does not have the information necessary to estimate the cost of applicable discounts for these plans and will not provide prospective Manufacturer Discount Program payments to EGWPs. We propose to codify this exception to the Manufacturer Discount Program prospective payments at § 423.2744(b).

However, because manufacturers are required to provide discounts for applicable drugs when dispensed to applicable beneficiaries who are enrolled in an EGWP, EGWPs are required to advance such discounts at the point of sale. The discounts will be invoiced to the manufacturer for reimbursement to the EGWP through the invoicing process at proposed § 423.2756(a).

c. Reconciliation

Because prospective discount payments are estimates, Part D sponsors may incur actual Manufacturer Discount Program costs that are greater or less than the prospective payments. To ensure that Part D sponsors are made whole for the manufacturer discount amounts they advanced on behalf of the manufacturer, we propose at § 423.2744(c) to codify cost-based reconciliation in accordance with subpart G of Part 423 and as implemented under section 60.5 of the Manufacturer Discount Program Final Guidance. Manufacturer Discount Program reconciliation occurs after Part D payment reconciliation. In general, CMS calculates the discount reconciliation amount by subtracting the prospective discount payments from manufacturer discount amounts as reported by Part D sponsors on PDE data and invoiced to manufacturers. If the difference is positive, CMS pays the difference to Part D sponsors. If the prospective discount payments exceed the invoiced manufacturer discount amounts, CMS recovers the difference from Part D sponsors. Manufacturer discount amounts reported on invoiced PDE data submitted by the PDE submission deadline for Part D payment reconciliation are included in the Manufacturer Discount Program reconciliation. Any manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for Part D payment reconciliation for a plan year are not subject to the Manufacturer Discount Program reconciliation process for that plan year.

d. Manufacturer Bankruptcy

In the event that an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, does not pay all invoiced amounts due under the requirements of proposed § 423.2756(a), we propose at § 423.2744(d) to adjust the Manufacturer Discount Program reconciliation amount for each affected Part D sponsor to account for the total unpaid quarterly invoiced amount owed to each Part D sponsor for the contract

year being reconciled, as per proposed § 423.2744(c). We propose to reserve the government's right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to attempt to recover such unpaid amounts and any civil money penalties imposed by CMS under these regulations.

11. Requirement To Use the Health Plan Management System (§ 423.2748)

The Health Plan Management System (HPMS) is CMS's primary system of record for the collection, review, and storage of information that must be submitted by Part D manufacturers for CMS review. As announced in the April 17, 2023 HPMS memorandum, "April 2023 Drug Manufacturer Module Enhancements,"²⁵ CMS modified the Drug Manufacturer Contract Management module in the HPMS in support of the IRA, including changes to support the Manufacturer Discount Program. CMS relies on ownership and other identifying information that agreement holders provide and attest to in the HPMS and in accordance with proposed § 423.2752(a)(7) for determining manufacturers' discount phase-in eligibility status and for other program operations.

We propose to codify the HPMS instructions included in the Manufacturer Discount Program Final Guidance, for program continuity and to minimize burden. Specifically, under proposed § 423.2748, agreement holders are required to use the HPMS to—

- Provide and maintain required information, as specified by CMS;
- Attest to the completeness and accuracy of the data necessary for CMS to determine whether the manufacturer qualifies as a specified manufacturer or specified small manufacturer, as described at § 423.2716;
- Execute a Manufacturer Discount Program agreement and a TPA agreement; and
- As otherwise specified by CMS to administer the program.

More information about the use of the HPMS for the Manufacturer Discount Program is provided in the Part D Manufacturer Discount Program Information Collection Request (ICR) (CMS–10846, OMB control no. 0938–1451), which was approved by the Office of Management and Budget through September 30, 2025. The Part D Manufacturer Discount Program ICR, including the supporting statement, information collection instruments, a

²⁵ Available at <https://www.cms.gov/https://editcmsgov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos/hpms-memos-wk-3-april-17-21>.

summary of changes, and responses to comments received during the comment periods can be viewed at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003 (select “all” to see full details). The ICR renewal package was published on June 20, 2025, for a 60-day public comment period, and was published again on October 2, 2025, for a 30-day public comment period.²⁶ CMS received no comments during either comment period, and the ICR renewal package has submitted to OMB for approval.

To comply with the requirements under proposed § 423.2748, agreement holders must obtain and maintain access in the HPMS. The May 4, 2023 HPMS memorandum entitled “Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)”²⁷ describes the steps involved in obtaining and maintaining access. These steps include requesting a CMS user identification and HPMS access, establishing HPMS access and electronic signature access, and annually recertifying identification and password requirements.

Because Part D sponsors are already required to maintain administrative and management capabilities sufficient for financial, communication, and other activities related to the delivery of Part D services, under existing § 423.505(b)(25), we have not proposed separate requirements in subpart AA regarding Part D sponsors’ use of HPMS.

12. Manufacturer Discount Program Agreement (§ 423.2752)

Section 1860D–14C(a) of the Act requires CMS to enter into Manufacturer Discount Program agreements with manufacturers in order for manufacturers to participate in the Manufacturer Discount Program. We propose to codify section 80.1 of the Manufacturer Discount Program Final Guidance at proposed § 423.2752.

CMS released the Manufacturer Discount Program agreement template on November 17, 2023. The burden associated with executing the agreement and related requirements is currently approved under OMB control number 0938–1451 (CMS–10846) and referenced in the COI section of this proposed rule.

a. Requirements of Agreement

As discussed in more detail in section II.C.4. of this preamble, a manufacturer is considered to participate in the Manufacturer Discount Program and to have entered into and have in effect a Manufacturer Discount Program agreement, as required under section 1860D–43(a) of the Act, if such manufacturer executes and has in effect its own Manufacturer Discount Program agreement or participates by means of an arrangement whereby its labeler code(s) is covered by another manufacturer’s Manufacturer Discount Program agreement that is in effect. We propose to codify this requirement at § 423.2708(b). We further clarify that only a manufacturer that is an agreement holder (as defined in § 423.2708) is a party to such agreement with CMS, and the entity subject to the rights and obligations of such agreement. In accordance with this framework, the requirements we propose at § 423.2752 related to the Manufacturer Discount Program agreement apply only to manufacturers that are agreement holders. Pursuant to section 1860D–14C(b) of the Act, we propose that the Manufacturer Discount Program agreement require, at a minimum, each agreement holder to:

- Reimburse, within the required 38-day timeframe, all applicable discounts provided by Part D sponsors on behalf of the manufacturer for applicable drugs dispensed on or after January 1, 2025 that have an NDC with a labeler code that is covered by the manufacturer’s Manufacturer Discount Program agreement and invoiced to the manufacturer. As proposed at § 423.2756(b)(2), when an invoice deadline falls on a Saturday, Sunday, or legal holiday, the payment timeframe is extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday.

- Provide CMS with all labeler codes covered by its Manufacturer Discount Program agreement.

- Ensure that the labeler codes provided to CMS include, at a minimum, all labeler codes assigned by the FDA to the manufacturer that contain NDCs for any of the manufacturer’s applicable drugs or selected drugs, and promptly update CMS with any labeler codes newly assigned to the manufacturer by the FDA that contain NDCs for any of the manufacturer’s applicable drugs or selected drugs in accordance with the timing requirements discussed later in this section and proposed at § 423.2756(c)(3) for newly assigned labeler codes.

- Comply with the requirements established by CMS for purposes of administering the Manufacturer Discount Program and monitoring compliance with such program, including providing the manufacturer’s Employer Identification Number (EIN) and other identifying information to CMS upon request.

- Comply with the requirements related to the provision and maintenance of data, including collecting, maintaining, and reporting appropriate data related to the labeler codes covered by its agreement and any other data CMS determines necessary to carry out the Manufacturer Discount Program and demonstrate compliance with its requirements.

- Enter into and have in effect, under the terms and conditions specified by CMS, an agreement with the TPA and comply with such agreement and all TPA instructions, processes, and requirements.

- Provide and attest to information, as specified by CMS, necessary for CMS to determine eligibility for, and implement, the specified manufacturer and specified small manufacturer phase-in discounts.

- Agree that, no less than 30 days after the date CMS determines that a primary manufacturer of a selected drug has, in accordance with proposed § 423.2752(c)(1)(ii), provided notice to CMS of its decision not to enter into or continue its participation in the Medicare Drug Price Negotiation Program and to discontinue its applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, none of the drugs of such primary manufacturer will be covered by the manufacturer’s Manufacturer Discount Program agreement.

- Comply with all other requirements of the Manufacturer Discount Program.

We propose to codify these requirements at § 423.2752(a).

b. Term and Renewal

Consistent with section 1860D–14C(b)(4)(A) of the Act, Manufacturer Discount Program agreements are valid for an initial term of not less than 12 months, and automatically renew for a period of 1 year on each subsequent January 1, except as described later in this section, unless terminated as described in section II.C.12.c. of this preamble. Under section 1860D–14C(b)(1)(C)(i) of the Act, a manufacturer must have entered into the agreement no later than March 1, 2024 to participate in the Manufacturer Discount Program in 2025. The initial

²⁶ Available at <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/prra-listing/cms-10846>.

²⁷ Available at <https://www.cms.gov/https://editcmsgov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos/hpms-memos-wk-1-may-1-5>.

12-month term began on January 1, 2025 and ends on December 31, 2025.

Consistent with the policies CMS established in the Manufacturer Discount Program Final Guidance, for subsequent years, we propose that a Manufacturer Discount Program agreement would become effective on the first day of a calendar quarter. We further propose that a manufacturer must enter into the agreement no later than the last day of the first month of a calendar quarter for the term to begin on the first day of the next calendar quarter. If a manufacturer enters into the agreement after the last day of the first month of a particular calendar quarter, the initial term would begin on the first day of the second calendar quarter after the calendar quarter in which the manufacturer entered into the agreement.

Under our proposal, an initial term that begins on January 1 would end on December 31 of the same calendar year. An initial term that begins on April 1, July 1, or October 1 would end on December 31 of the following calendar year. The following examples illustrate these proposed requirements:

- Manufacturer enters into agreement on October 31, 2027; agreement is effective on January 1, 2028 and the initial term ends on December 31, 2028.
- Manufacturer enters into agreement on November 1, 2027; agreement is effective on April 1, 2028 and the initial term ends on December 31, 2029.

We propose to codify the requirements related to the Manufacturer Discount Program agreement term and renewal at § 423.2752(b).

c. Termination of Agreement

(1) Termination by CMS

Under section 1860D–14C(b)(4)(B)(i) of the Act, CMS may terminate a Manufacturer Discount Program agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to a manufacturer's participation in the Manufacturer Discount Program. The statute also specifies that a termination by CMS will not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination. We propose to codify the policies for termination by CMS at § 423.2752(c)(1).

Consistent with applicable guidance for the Medicare Drug Price Negotiation Program,²⁸ a manufacturer that is a

primary manufacturer, as we propose to define at § 423.2704, may submit a request for termination of a Manufacturer Discount Program agreement in connection with a notice of its decision that it is unwilling to participate in, or continue its participation in, the Medicare Drug Price Negotiation Program.

Specifically, a manufacturer that is the primary manufacturer of a selected drug may provide a notice to CMS stating the primary manufacturer's unwillingness to participate in, or its request to terminate an agreement under, the Medicare Drug Price Negotiation Program (herein referred to as a "Request to Terminate"). In accordance with applicable regulations and guidance for the Medicare Drug Price Negotiation Program, such Request to Terminate must incorporate both: (1) a request for termination of the primary manufacturer's applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. 5000D(c)(1)(A)(i); and (2) an attestation that provides in part that through the end of the price applicability period (as defined in section 1191(b)(2) of the Act) for the selected drug that the primary manufacturer (i) shall not seek to enter into any subsequent agreement with the Manufacturer Discount Program under section 1860D–14C of the Act; and (ii) shall not seek coverage for any of its drugs under the Manufacturer Discount Program under section 1860D–14C of the Act, consistent with the requirements set forth in 26 U.S.C. 5000D(c)(1)(B). If CMS determines the primary manufacturer's Request to Terminate complies with applicable requirements, the primary manufacturer's request will constitute good cause under section 1860D–14C(b)(4)(B)(i) of the Act to terminate the primary manufacturer's applicable agreements under the Manufacturer Discount Program in accordance with

Security Act for Initial Price Applicability Year 2026, available at <https://www.cms.gov/files/document/revise-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>; the October 2, 2024 Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, available at <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>; and the September 30, 2025 Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, available at <https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

the proposed § 423.2752(c)(1)(ii) and the proposed § 423.2752(c)(1)(v)(A)(1), as applicable.²⁹ CMS also will terminate coverage for all of the drugs of the primary manufacturer under the Manufacturer Discount Program in accordance with proposed § 423.2752(c)(1)(v)(A)(2), as discussed in more detail later in this section.

Consistent with the requirement in section 1860D–14C(b)(4)(B)(i) of the Act and the termination policies established in section 80.1.3.1 of the Manufacturer Discount Program Final Guidance, CMS will provide, upon written request, a manufacturer a hearing concerning a termination by CMS. This hearing will take place prior to the effective date of the termination with sufficient time for the termination to be repealed prior to the effective date if CMS determines repeal would be appropriate. If a manufacturer or CMS receives an unfavorable decision from the hearing officer, the manufacturer or CMS may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. The decision of the CMS Administrator is final and binding. A timely request for a hearing before a hearing officer or review by the CMS Administrator will stay termination until the parties have exhausted their appeal rights under the Manufacturer Discount Program, which means either the timeframes to pursue a hearing before a hearing officer or review by the CMS Administrator have passed or a final decision by the Administrator has been issued and there is no remaining opportunity to request further administrative review. We propose to codify these policies regarding hearings at § 423.2752(c)(1)(iv)(A) and (B).

In the case of a primary manufacturer of a selected drug under the Medicare Drug Price Negotiation Program that is unwilling to enter into a Medicare Drug Price Negotiation Program agreement or continue its participation in the Medicare Drug Price Negotiation Program and submits a Request to Terminate that complies with all

²⁹ 26 U.S.C. 5000D(c)(2), as enacted by section 11003 of the IRA, defines "applicable agreement." In the context of the Manufacturer Discount Program, the primary manufacturer's applicable agreements include any Manufacturer Discount Program agreement for which the primary manufacturer is the agreement holder, as well as any arrangement in which FDA-assigned labeler code(s) of the primary manufacturer is/are covered under the Manufacturer Discount Program agreement of another manufacturer. If the primary manufacturer's Request to Terminate complies with applicable requirements, CMS will effectuate removal of only the previously described FDA-assigned labeler code(s) from the Manufacturer Discount Program agreement of another manufacturer.

²⁸ See, for example, sections 40.1 and 40.6, as applicable, of the June 30, 2023 Medicare Drug Price Negotiation Program Revised Guidance, Implementation of Sections 1191–1198 of the Social

applicable requirements, CMS shall, upon written request from such primary manufacturer, provide a hearing concerning the termination of the primary manufacturer's applicable agreements under the Manufacturer Discount Program, in accordance with section 1860D–14C(b)(4)(B)(i) of the Act. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers. CMS' determination that there is good cause for termination depends solely on the primary manufacturer's request for termination to effectuate its decision not to participate in or to terminate its participation in the Medicare Drug Price Negotiation Program. Therefore, the only question to be decided in the hearing is whether the primary manufacturer has asked to rescind its Request to Terminate prior to the effective date of the termination. CMS will automatically grant such request from the primary manufacturer to rescind its Request to Terminate. We propose to codify these policies at § 423.2752(c)(1)(iv)(C).

If CMS determines that a primary manufacturer's Request to Terminate complies with all applicable requirements, we will effectuate the removal of the FDA-assigned labeler code(s) of the primary manufacturer from all Manufacturer Discount Program agreements for which the primary manufacturer is not the agreement holder no earlier than 30 days from the date we send the notice of termination to the manufacturer in accordance with proposed § 423.2752(c)(1)(iii).

We propose to codify this requirement at § 423.2752(c)(1)(v)(A)(1).

Similarly, CMS will effectuate the termination of coverage under any Manufacturer Discount Program agreement specific to NDCs of all applicable drugs and selected drugs for which the primary manufacturer is the holder of the new drug application or biologics license application. Such termination of coverage will apply to all applicable drug and selected drug NDCs of the primary manufacturer for which the labeler code is assigned to a manufacturer other than the primary manufacturer and for which the primary manufacturer is the new drug application or biologics license application holder for such drug. We propose to codify this requirement at § 423.2752(c)(1)(v)(A)(2).

At § 423.2752(c)(1)(v)(B), we propose to clarify that, consistent with the requirement at § 423.2752(c)(3) discussed below, the removal of labeler code(s) in accordance with

§ 423.2752(c)(1)(v)(A)(1) and the termination of coverage specific to NDCs in accordance with § 423.2752(c)(1)(v)(A)(2) do not affect the agreement holder's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs with such labeler code(s) or such NDCs that were incurred under the agreement before the effective date of removal or termination.

(2) Termination by the Manufacturer

In accordance with section 1860D–14C(b)(4)(B)(ii) of the Act, an agreement holder may terminate its Manufacturer Discount Program agreement for any reason. Under the policies established in section 80.1.3.2 of the Manufacturer Discount Program Final Guidance, if the manufacturer provides notice of termination under section 1860D–14C(b)(4)(B)(ii) of the Act before January 31 of a calendar year, such termination will be effective as of January 1 of the succeeding calendar year. If the manufacturer provides such notice of termination on or after January 31 of a calendar year, the termination will be effective as of January 1 of the second succeeding calendar year. The following examples illustrate these requirements:

- If a manufacturer notifies CMS on January 20, 2027 that it wishes to terminate, the termination will be effective as of January 1, 2028.
- If the manufacturer notifies CMS on February 1, 2027 that it wishes to terminate, the termination will be effective as of January 1, 2029.

We propose to codify these existing policies without modification at § 423.2752(c)(2).

(3) Post-Termination Obligations

Consistent with section 1860D–14C(b)(4)(B)(iii) of the Act, the termination of a Manufacturer Discount Program agreement under either sections 1860D–14C(b)(4)(B)(i) or 1860D–14C(b)(4)(B)(ii) of the Act will not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with labeler code(s) covered by the manufacturer's agreement that were incurred under the agreement before the effective date of termination.

We propose to codify this requirement at § 423.2752(c)(3).

(4) Reinstatement

As described in section 80.1.4 of the Manufacturer Discount Program Final Guidance, reinstatement in the Manufacturer Discount Program subsequent to termination by CMS will be available to a manufacturer only

upon payment of all outstanding applicable discounts and penalties incurred under any previous Manufacturer Discount Program agreement or Coverage Gap Discount Program agreement. The timing of any such reinstatement will be consistent with the requirements for entering into an agreement under proposed § 423.2752(b).

We propose to codify this policy at § 423.2752(c)(4).

(5) Automatic Assignment Upon Change of Ownership

At § 423.2752(d) we propose to codify the requirements of section 80.5.1 of the Manufacturer Discount Program Final Guidance and section (VIII)(b) of the Manufacturer Discount Program agreement, that in the event of a change in ownership of a manufacturer that is an agreement holder, the Manufacturer Discount Program agreement is automatically assigned to the new owner, and all terms and conditions of the agreement remain in effect as to the new owner unless terminated in accordance with requirements at § 423.2752(c). Further, we propose that the new agreement holder would agree to be bound by and to perform all the duties and responsibilities under the Manufacturer Discount Program, and assume all obligations and liabilities of, and all claims incurred against, the prior agreement holder under the Manufacturer Discount Program agreement whether arising before or after the effective date of the change of ownership.

13. Manufacturer Requirements (§ 423.2756)

We propose that manufacturers that are agreement holders, as defined at § 423.2704, must comply with all requirements at proposed § 423.2756.

a. Manufacturer Invoicing

CMS established its manufacturer invoicing policy in section 80.2 of the Manufacturer Discount Program Final Guidance. We propose to codify this policy at § 423.2756(a). Specifically, we propose that CMS will calculate, based on information reported by Part D sponsors, the amounts owed for applicable discounts for applicable drugs having NDCs with a labeler code covered by the agreement holder's Manufacturer Discount Program agreement. We also propose that CMS will invoice agreement holders quarterly through the TPA's portal, consistent with the published invoicing

calendar.³⁰ Such invoices will be itemized at the NDC level. In addition, we propose that CMS will invoice manufacturer discount amounts from accepted PDE data for 37 months following the end of the benefit year.

CMS considered feedback from interested parties received prior to issuing the Manufacturer Discount Program Draft Guidance regarding data elements to include in manufacturer invoices. Based on this feedback, and in an effort to provide transparency and minimize manufacturer disputes, CMS includes the following detail on Manufacturer Discount Program invoices:

- Date of service;
- Service provider identifier qualifier;
- Service provider identifier;
- Prescription/service reference number;
- Product/service identifier;
- Quantity dispensed;
- Days supply;
- Fill number;
- Reported discount;
- Low-income cost sharing amount;
- Total gross covered drug cost accumulator;
- True out-of-pocket accumulator;
- Gross drug cost below out-of-pocket threshold; and
- Gross drug cost above out-of-pocket threshold.

b. Requirement for Timely Payment

We propose at § 423.2756(b)(1) that agreement holders must pay each Part D sponsor the invoiced amounts through the TPA portal no later than 38 calendar days from receipt of the relevant invoice, in the manner specified by CMS, with limited exceptions in proposed paragraphs (b)(2) and (b)(3). At § 423.2756(b)(2), we propose that if an invoice deadline falls on a Saturday, Sunday, or legal holiday, the payment timeframe is extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday.

At § 423.2756(b)(3), we propose that agreement holders are not permitted to withhold payment for any disputed invoiced amount, including while a dispute is pending, except when the basis for the dispute is that the agreement holder has been invoiced amounts for applicable drugs that have NDCs that do not correspond to labeler codes covered by the agreement holder's Manufacturer Discount Program agreement. Under the proposed regulation, if payment is withheld in

such an instance, the agreement holder must notify the TPA within 38 calendar days of the manufacturer's receipt of the applicable invoice that payment is being withheld for this reason.

This payment withholding rule is consistent with processes established in section 80.2.3 of the Manufacturer Discount Program Final Guidance, and we believe it continues to strike a reasonable balance between the needs of manufacturers and Part D sponsors. CMS performs extensive quality assurance with respect to PDE data submitted by sponsors and, based on our experience under the Coverage Gap Discount Program, we believe that prohibiting the withholding of disputed invoices minimizes the risk to Part D sponsors for these discount-related incurred liabilities without significantly increasing the financial risk to a manufacturer. The PDE data used to calculate quarterly invoices are derived from claims for each prescription submitted to Part D sponsors for payment. Part D sponsors validate each claim as part of their process to reimburse pharmacies for the cost of the drug. In addition, CMS applies multiple edits to validate the PDE data submitted by Part D sponsors. Those edits include identification and adjustment of outlier and other erroneous entries for variables, such as discount amount, beneficiary eligibility for the discount, and NDCs.

c. Reporting Requirements

At paragraph (c)(1) of § 423.2756, we propose that, in general, agreement holders must collect, have available, and maintain appropriate data related to the labeler codes covered by their Manufacturer Discount Program agreement. This includes FDA drug approvals, FDA NDC Directory listings, NDC last-lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines necessary to carry out the Manufacturer Discount Program and demonstrate compliance with its requirements. We also propose that manufacturers maintain such data as described previously for a period of not less than 10 years from the date of payment of the corresponding invoice. This 10-year timeline is consistent with the Part D record retention requirement for Part D sponsors at § 423.505(d).

At § 423.2756(c)(2), we propose requirements related to providing information to CMS about manufacturer ownership. Specifically, at paragraph (c)(2)(i), we propose to require agreement holders to provide and attest to ownership and other data, in the form

and manner specified by CMS, as necessary for CMS to determine eligibility for discount phase-ins for specified manufacturers and specified small manufacturers in accordance with statutory requirements, as we propose to codify at § 423.2716. Likewise, at paragraph (c)(2)(iii), we propose that if the agreement holder covers the FDA-assigned labeler code(s) of another manufacturer by its Manufacturer Discount Program agreement, the agreement holder would also be required to provide ownership information about such other manufacturer.

Similarly, it is imperative that CMS be notified promptly of any ownership changes of a manufacturer participating in the Manufacturer Discount Program so that CMS can evaluate such changes as they relate to the application of discount phase-ins, including the acquisition policy under proposed § 423.2724. At § 423.2756(c)(2)(ii), we propose to codify our longstanding policy that agreement holders notify CMS of a change in their ownership no later than 30 calendar days after the agreement holder executes a legal obligation for such an arrangement and no later than 45 calendar days prior to the change in ownership taking effect. At § 423.2756(c)(2)(iii), we propose a corresponding requirement that, if an agreement holder covers the labeler code(s) of another manufacturer by its Manufacturer Discount Program agreement, the agreement holder must notify CMS of a change in ownership of such other manufacturer.

If CMS is not notified of an ownership change, the original agreement holder will be invoiced and payment will have to be reconciled between the manufacturers involved in the transaction. CMS will not consider untimely notice of a change of ownership to be grounds for an agreement holder to dispute the invoiced amount.

At § 423.2756(c)(3), we propose requirements related to labeler codes. Consistent with the Manufacturer Discount Program Final Guidance, section 80.5.2, we propose at § 423.2756(c)(3)(i) that each agreement holder must cover by its agreement all labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs. We also propose at § 423.2756(c)(3)(ii) that, consistent with § 423.2708(b)(2), an agreement holder may cover by its Manufacturer Discount Program agreement applicable drugs or selected drugs with labeler code(s) assigned by the FDA to another manufacturer, provided the other

³⁰ Available at [https://tpadministrator.com/internet/tpaw3_files.nsf/F/TPACGDP_MDP_Calendar_2024-2028_12062024.pdf/\\$FILE/CGDP_MDP_Calendar_2024-2028_12062024.pdf](https://tpadministrator.com/internet/tpaw3_files.nsf/F/TPACGDP_MDP_Calendar_2024-2028_12062024.pdf/$FILE/CGDP_MDP_Calendar_2024-2028_12062024.pdf).

manufacturer has not executed and does not have in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

We propose that agreement holders must provide to CMS and maintain all required labeler code information as instructed by CMS. Specifically, we propose at § 423.2756(c)(3)(iii) to require agreement holders to provide to CMS the following labeler code information:

- All labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs; and
- All labeler codes assigned by the FDA to another manufacturer that the agreement holder covers by its agreement and for which the agreement holder agrees to pay discounts.

We also propose at § 423.2756(c)(3)(iv) that agreement holders must provide labeler codes newly assigned by the FDA to the agreement holder to CMS no later than 3 business days after receiving written notification of the newly assigned labeler code(s) from the FDA and in advance of providing any NDCs associated with such labeler codes to electronic database vendors.

As proposed at § 423.2756(c)(3)(v), agreement holders are responsible for maintaining the list of labeler codes covered by their agreement to ensure that it remains current on an ongoing basis. An agreement holder's failure to update labeler codes covered by its agreement does not change the agreement holder's responsibility to pay the amounts invoiced for applicable drugs. Specific instructions on how agreement holders are to submit information to CMS are available in the HPMS Drug Manufacturer Management User Manual.

As part of maintaining the list of labeler codes covered by their Manufacturer Discount Program agreement, agreement holders should submit a request in HPMS to terminate labeler codes where all of the NDCs are past the last lot expiration date. In order to submit the request, the agreement holder must attest in HPMS that the marketing end date on the FDA NDC SPL Data Elements file, defined by the FDA as the date of expiration of the last lot released to the marketplace, has passed for all applicable drugs and selected drugs associated with the labeler code. Termination of labeler codes where all of the NDCs are past the last lot expiration date differs from the process proposed at § 423.2752(c)(1)(v), which applies to the CMS termination of labeler codes and NDCs of a primary

manufacturer and is described in section II.C.12.c. of this preamble.

At § 423.2756(c)(4), we propose requirements related to maintenance of FDA records and related records. CMS relies on data available through the FDA to identify applicable drugs in the Manufacturer Discount Program. Accordingly, we propose at § 423.2756(c)(4)(i)(A) that agreement holders must ensure that all labeler codes assigned by the FDA to the agreement holder that contain NDCs for any of its applicable drugs or selected drugs are properly listed on the FDA NDC Directory. We propose at § 423.2756(c)(4)(i)(B) that agreement holders must electronically list all NDCs of their applicable drugs or selected drugs with the FDA in advance of commercial distribution of the product(s) so that CMS and plans can accurately identify applicable drugs once they are provided to pharmacies for distribution. Further, CMS proposes at § 423.2756(c)(4)(i)(C) that agreement holders must maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory. As we discussed in section 80.5.3 of the Manufacturer Discount Program Final Guidance, accurate NDC listings enable CMS and Part D sponsors to accurately identify applicable drugs. For this reason, updates to the FDA NDC Directory must precede NDC additions made to commercial electronic databases used for pharmacy claims processing.

In addition, we propose at § 423.2756(c)(4)(i)(D) that agreement holders must maintain up-to-date listings with the electronic database vendors to whom they provide their NDCs for pharmacy claims processing. Only manufacturers know the last-lot expiration dates for their NDCs and, therefore, the manufacturers are responsible for ensuring that these electronic database vendors are prospectively notified when NDCs no longer represent products that are still available on the market. A manufacturer's failure to provide appropriate advance notice to electronic database vendors may result in the agreement holder being responsible for discounts after the last-lot expiration date unless the manufacturer can document that it provided such appropriate advance notice to the database vendors, or the manufacturer has provided advance notice to the FDA of the marketing end date.

At § 423.2756(c)(4)(ii), we propose that if an agreement holder's Manufacturer Discount Program agreement covers labeler code(s) that are

assigned by the FDA to another manufacturer that participates in the Manufacturer Discount Program in accordance with § 423.2708(b)(2), the agreement holder must ensure that the requirements of this section are met with respect to such labeler codes.

At § 423.2756(d), we propose to codify existing CMS policy that permits agreement holders to transfer labeler code(s) between Manufacturer Discount Program agreements so long as the transfer is consistent with requirements of the proposed subpart AA and the Manufacturer Discount Program agreement and is approved by CMS. Among other requirements, such a transfer must be consistent with proposed § 423.2756(c)(3)(i), which requires all labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs to be covered by the agreement holder's Manufacturer Discount Program agreement. Specifically, consistent with section 80.5.2.2 of the Manufacturer Discount Program Final Guidance, agreement holders are permitted to transfer existing labeler code(s) from one Manufacturer Discount Program agreement to another Manufacturer Discount Program agreement provided that both agreement holders take part in the transfer process. As instructed by CMS in the HPMS Drug Manufacturer Management User Manual, the agreement holder that covers under its Manufacturer Discount Program agreement the labeler code(s) of another manufacturer must request that the labeler code(s) be transferred to the other agreement holder, and the agreement holder that intends to assume coverage by its agreement must request that the labeler code(s) be added to its Manufacturer Discount Program agreement. If both agreement holders are in agreement and all other Manufacturer Discount Program requirements are met, CMS will approve the labeler code transfer between agreements by approving both agreement holders' requests. Transfers of labeler codes from one Manufacturer Discount Program agreement to another are not considered complete until CMS has approved both requests. The agreement holder seeking to transfer the labeler code from its agreement remains liable for payment of all discounts related to such labeler code until the transfer is complete. An agreement holder is not permitted to transfer its own FDA-assigned labeler code(s) to the Discount Program agreement of another manufacturer.

Once the transfer is complete, the receiving agreement holder assumes responsibility for all Manufacturer

Discount Program requirements with respect to the transferred labeler code(s). Manufacturer Discount Program invoices to the receiving agreement holder will include the discount amounts by labeler code for the entire quarter. If an agreement holder assumes liability for a labeler code effective the second or third month of a quarter, that agreement holder will be invoiced and is responsible for all discount amounts of that labeler code for the entire quarter, including any claims from dates of service in prior quarters that are included on that quarter's invoice. For example:

- If a labeler code transfer request is approved by CMS in February and becomes effective on March 1st, the first quarter (Q1) invoice will be delivered to the receiving agreement holder that assumed responsibility for the labeler code.

- If a labeler code transfer request is approved by CMS in March and becomes effective April 1st, the Q1 invoice will be delivered to the prior (that is, transferring) agreement holder.

In the event that business needs do not coincide with the timing of the transfer, agreement holders are expected to reconcile any payments among themselves without CMS involvement.

The transfer of a labeler code between Manufacturer Discount Program agreements includes all NDCs associated with the transferred labeler code; CMS will not transfer individual NDCs.

14. Audits (§ 423.2760)

We propose, at § 423.2760, to codify the Manufacturer Discount Program audit processes established in section 90 of the Manufacturer Discount Program Final Guidance. Such processes conform with section 1860D–14C(c)(2) of the Act, which requires CMS to monitor a manufacturer's compliance with the terms of a Manufacturer Discount Program agreement, and with section 1860D–14C(b)(2) of the Act, which requires manufacturers to collect and have available appropriate data, as determined by CMS, to ensure they can demonstrate to CMS compliance with the requirements of the Manufacturer Discount Program. Though the Act does not specifically allow audits by agreement holders, CMS proposes codifying that under CMS's authority to provide for implementation of the Manufacturer Discount Program under section 1860D–14C(d)(1) of the Act, CMS will permit agreement holders to conduct periodic audits of the TPA data and information used to calculate the quarterly invoices described in § 423.2756(a). CMS believes that

continuing to permit audits in the manner established under the Medicare Part D Manufacturer Discount Program Final Guidance promotes transparency as well as consistency in Part D program operations.

Specifically, we propose at § 423.2760(a)(1) that an agreement holder may conduct audits, directly or through third parties and no more often than annually, of TPA data and information used to determine discounts for applicable drugs covered under the agreement holder's Manufacturer Discount Program agreement. As proposed at § 423.2760(a)(2), the agreement holder must provide 60 calendar days' notice to the TPA of the reasonable basis for the audit and a description of the information required for the audit.

When developing audit processes for the Manufacturer Discount Program Final Guidance, CMS considered feedback from interested parties. In response to this feedback and in alignment with section 90.1.2 of the Manufacturer Discount Program Final Guidance, CMS provides the following data to agreement holders that are auditing TPA data, in addition to the data elements included on invoices:

- Contract number;
- Plan benefit package identifier;
- Ingredient cost paid;
- Dispensing fee paid;
- Total amount attributed to sales tax;
- Non-covered plan paid amount; and
- Vaccine administration fee or additional dispensing fee.

CMS proposes limits on audits of TPA data and information at § 423.2760(a)(3). To appropriately balance transparency and efficiency, and in alignment with generally accepted auditing standards, we propose at § 423.2760(a)(3)(i) that the data provided to the manufacturer conducting the audit be limited to a statistically significant random sample of data held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with labeler codes covered by the agreement holder's Manufacturer Discount Program agreement. Such data is sufficient for a manufacturer to reach statistically valid conclusions that could be used to support a dispute under proposed § 423.2764(a). We further propose at § 423.2760(a)(3)(ii) that manufacturers are not permitted to audit CMS records or the records of Part D sponsors beyond the data provided to the TPA, which includes claim-level information.

CMS is obligated to protect the privacy of beneficiary medical information. Accordingly, CMS proposes at § 423.2760(a)(3)(iii) that

audits must occur on site at a location specified by the TPA, and with the exception of work papers, such data cannot be removed from the audit site. Additionally, CMS proposes at § 423.2760(a)(3)(iv) that the auditor may release only an opinion of the audit results and is prohibited from releasing any other information obtained from the audit, including work papers, to its client, employer, or any other party. CMS believes these limitations on the distribution of data support beneficiary privacy, while addressing manufacturer need for access to data that are relevant to the calculation of the discounts.

Regarding CMS audits of manufacturer data, we propose at § 423.2760(b)(1) that an agreement holder is subject to periodic audit by CMS no more often than annually, directly or through third parties. We propose at § 423.2760(b)(2) that CMS must provide agreement holders with 60 calendar days' notice of the reasonable basis for the audit and a description of the information required for the audit. We further propose at § 423.2760(b)(3) that CMS has the right to audit appropriate data, including data related to labeler codes covered by the agreement holder's Manufacturer Discount Program agreement and related NDC last-lot expiration dates, utilization, and pricing information relied on by the agreement holder to dispute quarterly invoices, and any other data CMS determines necessary to evaluate compliance with the requirements of the Manufacturer Discount Program.

15. Dispute Resolution (§ 423.2764)

Section 1860D–14C(c)(1)(D) of the Act requires CMS to provide a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, Part D sponsors, and the Secretary. For continuity and familiarity, CMS proposes codifying the dispute resolution processes established in section 100 of the Manufacturer Discount Program Final Guidance.

Specifically, at § 423.2764, we propose a 3-level dispute resolution framework through which agreement holders can dispute applicable discounts that they were invoiced via the invoicing process proposed at § 423.2756(a). Such invoices may contain applicable discounts that an agreement holder believes are incorrect and which the agreement holder wishes to contest.

We propose at § 423.2764(a) that an agreement holder may dispute applicable discounts invoiced to such agreement holder under § 423.2756(a) by filing an initial dispute. This is the

first level of the dispute resolution framework. Under proposed § 423.2764(a)(1), the initial dispute must be filed in the manner specified by CMS no later than the dispute submission deadline, which CMS proposes to define at § 423.2704 as the date that is 60 calendar days from the date of the invoice containing the information that is the subject of the dispute. The disputing manufacturer must explain why it believes the invoiced discount amount is in error and must provide supporting evidence that is material, specific, and related to the dispute. We propose at § 423.2764(a)(2) that CMS will issue a written determination on an initial dispute no later than 60 calendar days from the dispute submission deadline.

We propose at § 423.2764(b) that an agreement holder that receives an unfavorable determination from CMS on its initial dispute, or that has not received a determination within 60 calendar days of the dispute submission deadline, may request review by the independent review entity (IRE) contracted by CMS. Such independent review is considered the second level of the dispute resolution framework.

We propose at § 423.2764(b)(1) that an agreement holder must file a request for review by the IRE in the manner specified by CMS no later than the earlier of 30 calendar days from the date of the unfavorable determination on the initial dispute, or 90 calendar days from the dispute submission deadline if no determination was made within 60 calendar days of the dispute submission deadline.

We propose at § 423.2764(b)(2) that the IRE may seek additional information from any agreement holder that requests an independent review, for the purpose of considering the appeal. An agreement holder's failure to comply with an information request from the IRE within the timeframe specified could result in the IRE issuing a denial. In addition to the information provided by the agreement holder, the IRE will base its decision on information received by CMS, the TPA, the Part D sponsor, and other databases compiled by CMS or other sources.

We propose at § 423.2764(b)(3) that the IRE will issue a written notice of decision to the agreement holder and to CMS no later than 90 calendar days from receipt of the request. Under proposed § 423.2764(b)(4), the notice must include a clear statement indicating whether the decision is favorable or unfavorable to the agreement holder; an explanation of the rationale for the IRE's decision; and instructions on how to request a review

by the CMS Administrator. Under proposed § 423.2764(b)(5), a decision by the IRE is binding on all parties unless the agreement holder or CMS files a valid request for review by the CMS Administrator.

At § 423.2764(c)(1), we propose as the third level of the dispute resolution process that an agreement holder or CMS may request review by the CMS Administrator following receipt of an unfavorable determination from the IRE. Under proposed § 423.2764(c)(2), such request must be filed in the manner specified by CMS, no later than 30 calendar days from the date of the IRE decision. After completing the review and making a decision, under proposed § 423.2764(c)(3), the CMS Administrator will issue written notice of their decision to both parties. Such decision by the CMS Administrator is final and binding under proposed § 423.2764(c)(4). CMS proposes at § 423.2764(d) that it will adjust future invoices, or implement an alternative reimbursement process if determined necessary, if a dispute is resolved in favor of the agreement holder. As discussed earlier in this preamble at II.C.13.b., CMS proposes at § 423.2756(b)(3) that agreement holders cannot withhold payment for any disputed invoiced amount, including while a dispute is pending, except as specified at § 423.2756(b)(3).

Under proposed § 423.2764(e) agreement holders cannot use this dispute resolution process to dispute a decision by CMS to terminate an agreement holder's participation in the Manufacturer Discount Program under § 423.2752(c)(1) or a decision by CMS about a manufacturer's eligibility for discount phase-ins described at § 423.2720. As described earlier in this section of the preamble, the dispute resolution process must be used specifically for the purpose of resolving disputes regarding applicable discounts invoiced to agreement holders under § 423.2756(a).

Under section 100.2 of the Manufacturer Discount Program Final Guidance, CMS does not permit Part D sponsors to dispute invoiced amounts under the Manufacturer Discount Program. Section 423.505(f) requires sponsors to submit information to CMS that is necessary for CMS to administer and evaluate the Part D program, which includes information relevant to disputes under the Manufacturer Discount Program. CMS relies on the information received in PDE data submitted by sponsors when applicable discounts are advanced at the point of sale for calculating quarterly invoices for agreement holders. Because sponsors

provide the data CMS uses to calculate invoices for agreement holders, sponsors do not have the right to directly dispute invoiced amounts under the processes described in this section. Part D sponsors should note that a determination about a dispute at any level of the dispute resolution process described in this section also cannot be appealed directly by a sponsor. However, as part of the adjudication process for manufacturer disputes, sponsors will have an opportunity to confirm the accuracy of a disputed discount, when applicable.

Regarding beneficiary disputes, the IRA does not require a dispute resolution mechanism for Part D enrollees with respect to the Manufacturer Discount Program and, as a practical matter, an individual would likely not be aware if a discount is provided on their claim, because in most cases, the Manufacturer Discount Program will not affect enrollee cost sharing, and consistent with section 1860D–14C(g)(4) of the Act, applicable discounts are not counted toward an enrollee's incurred costs. Nevertheless, any Part D enrollee who has a dispute about their plan's decision not to provide or pay for a Part D drug, including a dispute about whether a drug is excluded from Part D or about the amount of cost sharing, has the right to request a coverage determination from the plan and the right to appeal any coverage determination not fully favorable to the enrollee under the procedures specified in subpart M of part 423.

16. Civil Money Penalties (§§ 423.1000, 423.1002 and 423.2768)

Section 1860D–14C(e) of the Act requires that a manufacturer that fails to provide, in accordance with the terms of its Manufacturer Discount Program agreement and the requirements of the Manufacturer Discount Program, applicable discounts for applicable drugs covered by the manufacturer's Manufacturer Discount Program agreement and dispensed to applicable beneficiaries is subject to a civil money penalty (CMP) for each such failure. CMS proposes codifying this general rule at § 423.2768(a), in alignment with processes established in section 120 of the Manufacturer Discount Program Final Guidance.

Under proposed § 423.2756(b)(1), agreement holders must pay invoiced amounts to relevant Part D sponsors within 38 calendar days of receipt of a TPA invoice. CMS considers an agreement holder to have failed to provide applicable discounts if payment is not made within 38 calendar days,

with limited exceptions as proposed at § 423.2756(b)(2) and (b)(3). It is imperative that agreement holders make timely payments under the Manufacturer Discount Program, and an agreement holder's failure to establish sufficient controls to ensure compliance with this requirement will not relieve the agreement holder of penalties imposed under section 1860D–14C(e)(1) of the Act.

We propose at § 423.2768(b) that CMS will issue a notice of non-compliance to an agreement holder that fails to make a timely payment as required under § 423.2756(b). We propose allowing the agreement holder 5 business days to respond to the notice of non-compliance with additional context, evidence refuting the violation, or other factors that CMS may consider when determining whether to impose a CMP.

Consistent with section 1860D–14C(e)(1) of the Act, we propose at § 423.2768(c) that a CMP will be equal to the sum of the amount the agreement holder would have paid with respect to the applicable discount, plus 25 percent of such amount. In situations where an agreement holder pays an invoice in part, but not in full, within the required timeframe, any CMP imposed by CMS would be based only on the outstanding invoiced amount that was not paid within the required timeframe. Additionally, while the amount of a CMP may be reduced by any invoiced amount the agreement holder pays after the 38-day timeframe, such late payments will not relieve the agreement holder of its obligation to pay the additional 25 percent penalty, which will be assessed on all invoiced amounts not paid within the required timeframe, as proposed at § 423.2756(b).

We propose at § 423.2768(d) that, if after issuing a notice of non-compliance CMS makes a determination to impose a CMP on an agreement holder, CMS will send to such agreement holder a written notice of the determination to impose a CMP. Under our proposal, CMS would include the following 6 elements in the notice: a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the agreement holder's right to a hearing according to the administrative appeal process and procedures established in 42 CFR part 423, subpart T, and information about where to file the request for a hearing.

To ensure a consistent approach to CMPs, we propose at § 423.2768(e) applying existing appeal procedures for CMPs in 42 CFR part 423, subpart T to agreement holders appealing a CMP imposed under the Manufacturer

Discount Program. CMS has utilized this appeal process for many years for CMP determinations affecting MA organizations and Part D sponsors, including with respect to the Manufacturer Discount Program under the Manufacturer Discount Program Final Guidance. CMS therefore proposes to amend regulations in 42 CFR part 423, subpart T by replacing paragraph § 423.1000(a)(3), with new paragraphs (a)(3)(i) and (a)(3)(ii). Our proposed revisions would specify that CMS must impose a CMP on a manufacturer that fails to provide applicable discounts for applicable drugs of the manufacturer pursuant to both the terms of such manufacturer's Coverage Gap Discount Program agreement and such manufacturer's Manufacturer Discount Program agreement.

We also propose to amend the definition of “affected party” at § 423.1002 to conform to other regulatory changes proposed in this rule. Currently “affected party” is defined, in part, to include a “any manufacturer (as defined in § 423.2305)”. As discussed in section II.C.3. of this preamble, however, we are proposing to revise and move the definition of “manufacturer” from § 423.2305 to § 423.100. As such, we propose to revise the definition of “affected party” to refer to “for purposes of the Coverage Gap Discount Program, any manufacturer (as defined in § 423.100)”. For purposes of the Manufacturer Discount Agreement, the appeal procedures in 42 CFR part 423, subpart T could apply only to a manufacturer that is an “agreement holder” since an “agreement holder,” as defined at proposed § 423.2704, is a manufacturer that has executed and has in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1). As such, we further propose to revise the definition of “affected party” at § 423.1002 to specify “for purposes of the Manufacturer Discount Program, any manufacturer that is an agreement holder (as defined in § 423.2704)”.

Section 1128A(c)(2) of the Act specifically requires that CMS not collect a CMP until the affected party has received written notice and been given an opportunity for a hearing. Accordingly, we propose to codify at § 423.2768(f)(1) that CMS may not collect a CMP until the affected party (as defined at § 423.1002) has received notice and the opportunity for a hearing under section 1128A(c)(2) of the Act.

We propose to codify timing requirements for collecting CMPs that are assessed under the Manufacturer Discount Program in alignment with

section 120.3 of the Manufacturer Discount Program Final Guidance and with existing CMP appeal procedures codified in 42 CFR part 423, subpart T. Specifically, we propose at § 423.2768(f)(2) that an agreement holder that has received from CMS a notice of determination to impose a CMP must pay such CMP in full within 60 calendar days of the date of the CMS notice of determination, except as provided in § 423.2768(f)(3). At § 423.2768(f)(3), we propose that if the agreement holder requests a hearing to appeal in accordance with 42 CFR part 423, subpart T, the CMP is due, as applicable, once the administrative process specified in subpart T has concluded. We further propose at § 423.2768(f)(4) that CMS will initiate the collection of a CMP owed by an agreement holder either following the expiration of 60 days from the date of the CMS notice of determination to impose a CMP, or, if later, the conclusion of the administrative process specified in 42 CFR part 423, subpart T, as applicable.

Section 1860D–14C(e)(2) of the Act makes the provisions of section 1128A of the Act (except for subsections (a) and (b) of section 1128A of the Act) applicable to CMPs imposed under the Manufacturer Discount Program. We propose to codify this requirement at § 423.2768(g).

At § 423.2768(h), we propose that, in the event an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and, as a result of such bankruptcy, fails to pay the total sum of the CMPs imposed, the government reserves the right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to attempt to recover such unpaid amounts and any CMPs imposed by CMS under these proposed regulations.

17. Severability

The Manufacturer Discount Program provisions proposed herein are separate and severable from one another. If any of these provisions, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it is our intention that such provision shall be severable from this rule and not affect the remainder thereof, or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

D. Definition of Creditable Coverage

Section 1860D–13(b) of the Act contains provisions related to late enrollment penalties (LEPs), which are

increases in monthly beneficiary premiums for individuals without creditable coverage for a continuous period of Part D eligibility of 63 days or longer prior to Part D enrollment. Per section 1860D–13(b)(5) of the Act, coverage meets the creditable coverage requirement “only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage.”

The allowable methodologies used to determine creditable coverage have been updated a few times since the start of the Part D program, including most recently for CY 2025 and CY 2026 in the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions.³¹ Under changes to Part D made by the IRA, the definition of creditable prescription drug coverage at § 423.56(a) was modified in these Program Instructions. Prior to the Final CY 2025 Part D Redesign Program Instructions, § 423.56(a) specified that prescription drug coverage would be considered creditable “only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.” We now describe historical changes to the creditable coverage definition and allowable methodologies in greater detail.

Since the start of the Part D program in 2006, CMS, consistent with section 1860D–13 of the Act, has permitted an entity offering a group health plan that is not applying for the retiree drug subsidy (RDS) under section 1860D–22(a) of the Act³² to use either actuarial

equivalence testing or the creditable coverage “simplified determination methodology” to determine whether its prescription drug coverage is creditable. Some group health plans would undertake considerable workloads in conducting in-house actuarial testing, while others would use the simplified approach presented in the “Updated Creditable Coverage Guidance,” which we released on September 18, 2009. Under the simplified approach, coverage would be considered creditable if it:

- Provides coverage for brand and generic prescriptions;
- Provides reasonable access to retail providers;
- The plan is designed to pay on average at least 60 percent of participants’ prescription drug expenses; and
- Satisfies at least one of the following:

++ The prescription drug coverage has no annual benefit maximum or a maximum annual benefit payable by the plan of at least \$25,000, or

++ The prescription drug coverage has an actuarial expectation that the amount payable by the plan will be at least \$2,000 annually per Medicare eligible individual.

++ For entities that have integrated health coverage, the integrated health plan has no more than a \$250 deductible per year, has no annual benefit maximum, or a maximum annual benefit payable by the plan of at least \$25,000, and has no less than a \$1,000,000 lifetime combined benefit maximum.

The IRA eliminated the coverage gap phase and sunset the Coverage Gap Discount Program (CGDP) effective December 31, 2024. The Medicare Part D Manufacturer Discount Program (Manufacturer Discount Program) replaced the CGDP beginning January 1, 2025. The IRA revised section 1860D–22(a)(2)(A) of the Act to specify that any discount provided pursuant to the Manufacturer Discount Program established by the IRA under section 1860D–14C of the Act is not taken into account when determining the actuarial value of qualified retiree coverage. Additionally, section 1860D–14C(g)(1)(B) of the Act excludes enrollees in a qualified retiree prescription drug plan from the definition of applicable beneficiary for the purposes of the Manufacturer Discount Program. The changes made by the IRA required us to revise the existing regulatory definition of

creditable prescription drug coverage in § 423.56(a). Under the requirement in section 11201(f) of the IRA that we use program instruction or other forms of program guidance to implement section 11201 of the IRA for 2025 and 2026, we issued a revised regulatory definition of creditable prescription drug coverage in § 423.56(a) in the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions. In 2025 and 2026, the definition of creditable coverage reads as follows (bolded and italicized text indicates the language we added in light of the IRA):

Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount ***provided under section 1860D–14C of the Social Security Act***, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

In the Draft CY 2025 Part D Redesign Program Instructions, we proposed that because of the IRA changes to the Part D benefit, the simplified determination methodology would no longer be a valid methodology to determine whether such an entity’s prescription drug coverage is creditable as of 2025. For instance, the increased plan liability in the catastrophic phase of the defined standard benefit requires sponsors to pay more than the 60 percent specified in the current simplified determination methodology and, therefore, continuing to use 60 percent would not satisfy requirements for actuarial equivalence for creditable coverage. We received several comments on the Draft CY 2025 Part D Redesign Program Instructions that raised concerns about the potential risk that a large number of Part D eligible individuals would no longer have creditable coverage through their group health plan if the existing simplified determination methodology were no longer available for 2025. Commenters were also concerned that group health plan sponsors would not have sufficient time to consider the impact of the Part D benefit changes made by the IRA to make decisions about their benefit offerings in time for 2025 coverage.

In response to those comments, in the Final CY 2025 Part D Redesign Program Instructions we recognized the IRA’s sweeping changes to the Part D benefit in CY 2025, which, if coupled with the retirement of the creditable simplified

³¹ Draft CY 2025 Part D Redesign Program Instructions available at <https://www.cms.gov/files/document/draft-cy-2025-part-d-redesign-program-instruction.pdf>.

Final CY 2025 Part D Redesign Program Instructions available at <https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf>.

Draft CY 2026 Part D Redesign Program Instructions available at <https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf>.

Final CY 2026 Part D Redesign Program Instructions available at <https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf>.

³² The attestation of actuarial equivalence requirements for qualified retiree prescription drug plans (also known as plans receiving the Retiree

Drug Subsidy) are set forth in section 1860D–22 of the Act and codified in § 423.884.

determination methodology, could pose various challenges for group health plan sponsors and could have an adverse effect on certain Part D eligible individuals who could lose creditable coverage and be at risk for the Part D LEP. After consideration of the comments received and available options to mitigate potential disruptive effects of the Part D redesign on the group health plan market and the Part D eligible individuals served by such group health plans, we decided to continue to permit use of the creditable coverage simplified determination methodology, without modification to the existing parameters, for CY 2025 for group health plan sponsors not applying for the RDS. By permitting continued use of the creditable coverage simplified determination methodology for 2025, we stated we would have additional time to better assess the various impacts of the Part D redesign and evaluate modifications to this methodology to ensure Part D eligible individuals with creditable coverage continue to have prescription drug coverage that is at least as good as defined standard Part D coverage. We committed to re-evaluating the continued use of the existing simplified determination methodology, or establish a revised one, for 2026.

For 2026, the Final CY 2026 Part D Redesign Program Instructions adopted a revised simplified determination methodology for non-RDS group health plans to determine whether their prescription drug coverage is creditable. Under the revised simplified determination methodology, coverage is deemed to provide prescription drug coverage with an actuarial value that equals or exceeds the actuarial value of defined standard Part D coverage if it meets all of the following standards:

- Provides reasonable coverage for brand name and generic prescription drugs and biological products;
- Provides reasonable access to retail pharmacies; and
- Is designed to pay on average at least 72 percent of participants' prescription drug expenses.

The revised simplified determination methodology retained some parameters of the prior methodology, such as a requirement for reasonable coverage of brand and generic prescription drugs and reasonable retail pharmacy access. We added coverage of biological products due to changes in the prescription drug landscape since the prior methodology was developed and made other updates for accuracy. We removed the requirements related to annual and lifetime benefit maximums because changes to the health insurance

landscape under the Affordable Care Act have essentially eliminated such limitations among group health plans. We also removed requirements related to an annual deductible, because outside of the Medicare program it is unusual for health and drug coverage to be separate benefits, and integrated health and drug plans could have a significantly higher deductible than standard Part D coverage but still offer comparable drug coverage. Although plans with higher annual deductibles (including high deductible health plans) might have appeared less likely to meet the requirement to pay at least 72 percent of prescription drug expenses, such risk may be mitigated through other aspects of the benefit such as not applying a deductible to preventive (that is, maintenance) medications, a reasonable and supportable allocation of the deductible attributable to prescription drug expenses, or offering lower cost sharing than standard Part D coverage once the deductible is met.

Under the revised simplified methodology for 2026, the group health plan coverage must be designed to pay at least 72 percent of participants' prescription drug expenses, versus 60 percent under the prior methodology. We made this revision because of program changes in Part D—in particular, the benefit changes mandated by the IRA, which significantly enhanced the Part D defined standard benefit. These changes—which included a \$35 cost sharing cap on a month's supply of each covered insulin product, access to recommended adult vaccines without cost sharing, the implementation of an annual out-of-pocket threshold (\$2,100 for CY 2026), and the elimination of the coverage gap phase of the benefit—increased the proportion of drug costs paid by the Part D plan sponsor. In light of the more robust Part D benefit under the IRA, we determined that the 60 percent value was no longer an accurate representation of the value of the Part D benefit and that group health plan coverage for 2026 should be designed to pay on average at least 72 percent of participants' prescription drug expenses in order to provide coverage to the individual that equals or exceeds the actuarial value of standard Part D coverage, as required by section 1860D–13(b)(5) of the Act. We estimated the actuarial value of the defined standard benefit in 2026 using 2023 Part D claims experience under the projected 2026 benefit structure. The 2026 benefit parameters were deflated to a 2023 dollar basis. We estimated that the actuarial value increased to 72 percent,

primarily as a result of the changes made by the IRA to the Part D defined standard benefit.

The Draft CY 2026 Part D Redesign Program Instructions stated that non-RDS group health plans could make the determination of creditable coverage either by (1) determining whether the actuarial value of the coverage equals or exceeds the actuarial value of defined standard Part D coverage, demonstrated through generally accepted actuarial principles, or (2) using the revised simplified determination methodology described previously. In response to comments received requesting a phased in approach to this change, in the Final CY 2026 Part D Redesign Program Instructions, we decided to allow for a transition year whereby non-RDS group health plans that opted to make the determination of creditable coverage through the simplified determination methodology were permitted for 2026 to use either the 2009 simplified determination methodology (that is, among other requirements, at least 60 percent of prescription drug expenses) or the revised simplified determination methodology (that is, among other requirements, at least 72 percent of prescription drug expenses) to determine whether their prescription drug coverage is creditable. We determined that this transitional policy for CY 2026 was appropriate to minimize potential risks to the employer group market and to Part D eligible individuals who may no longer have access to creditable coverage through an employer plan. In the Final CY 2026 Part D Redesign Program Instructions, we also stated our intention to propose to no longer permit use of the 2009 simplified determination methodology for CY 2027.

As the IRA's directive to implement the Part D redesign by program instruction or other forms of program guidance expires in 2027, we propose codifying in § 423.56(a) the revised definition of creditable coverage in the Final CY 2026 Part D Redesign Program Instructions to account for the Manufacturer Discount Program. We also propose to amend § 423.56(a) to sunset use of the 2009 simplified determination methodology and codify the revised simplified determination methodology, starting with 2027. In § 423.56(a), we propose to require that non-RDS group health plans may either use actuarial equivalence testing under § 423.56(a)(1) or the revised simplified determination methodology under § 423.56(a)(2) and in place for CY 2026, with one modification from 72 to 73 percent of prescription drug costs the

non-RDS group health plan must cover compared with coverage under a Part D defined standard plan.

To determine the percent of prescription drug costs that must be covered to be creditable, our modeling is based on the prescription drug event (PDE) data for a recent year. We modify the claims line by line to adjust for benefit differences while maintaining actual utilization patterns. For the purposes of determining what the simplified determination value should be for a given future year, we readjudicate all claims as they would have been paid under the defined standard benefit design for the year we are projecting. This process also requires estimating the benefit parameters for the year of interest and deflating the values to align with the historical PDE experience year we are using in our projection. After the PDE records are adjusted to the benefit design of the future year, we aggregate the results to determine the average percentage of gross drug cost that would be covered by a defined standard plan. We use this value rounded to the nearest whole percentage point as the minimum percent of participants' prescription drug expenses that the non-RDS health plan benefit needs to be designed to pay in order to qualify as creditable coverage.

As discussed and consistent with the methodology described previously in this section, we estimated the actuarial value of the defined standard benefit for 2026 using 2023 Part D claims experience under the projected 2026 benefit levels deflated to a 2023 dollar basis to arrive at the requirement that a non-RDS health plan's benefit must be designed to pay on average 72 percent of participants' prescription drug expenses to meet the conditions of the revised simplified determination methodology. For 2027, this model estimates an actuarial value of 73 percent for the defined standard benefit. In subsequent years, this value is projected to increase, ultimately reaching 75 percent in 2030 and stabilize thereafter. Accordingly, we propose a minimum of 73 percent instead of 72 percent for 2027. We further propose that we will update this figure for future years in a time and manner as we determine, consistent with the actuarial equivalence requirements in section 1860D–13(b)(5) of the Act and the methodology described earlier in this section, via subregulatory guidance, such as a memo issued by the Health Plan Management System (HPMS). We would release this guidance in advance of the yearly bid submission deadline for plan sponsors

to take into account as they prepare their bids.

As described previously, the proposed changes to § 423.56 retire the simplified approach presented in the “Updated Creditable Coverage Guidance” that we released on September 18, 2009, and generally proposes to codify the options available to plans in the Final CY 2026 Part D Redesign Program Instructions: choosing between conducting actuarial equivalence testing themselves or the revised simplified determination methodology. Non-RDS plans using either approach in the proposed § 423.56(a) can attest to the creditable coverage of their plan offerings, thereby ensuring individuals in creditable non-RDS plans will not owe an LEP upon enrollment in a Part D plan. The proposed § 423.56 requirements have mostly been previously implemented and our proposal in this rulemaking is similar to the ways plans assessed creditable coverage in 2026. We do not believe that the proposed changes to the regulatory text would have a significant impact on plan sponsors or individuals. There is no change to paperwork burden to plans or individuals.

E. Outlier Prescriber Criteria

1. Background

Section 6065 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) added subparagraph (D) to section 1860D–4(c)(4) of the Act, which requires the Secretary to identify Part D outlier prescribers of opioids, using the valid prescriber National Provider Identifier (NPI) included on claims for covered part D drugs, and notify those prescribers that they have been identified as outliers. The notifications provided to prescribers identified as outliers include information on how the prescriber compares to other prescribers within the same specialty and geographic area, as well as resources on proper prescribing methods.

The Secretary is required to establish thresholds for identifying whether a prescriber is an outlier based on prescribers in the same specialty and geographic area, with certain exclusions. We currently define outlier prescribers as those in the top 25th percentile when compared to their peers (that is, prescribers in the same National Plan & Provider Enumeration System (NPPES) taxonomy and State) for both (1) co-prescribing opioids and benzodiazepines, and (2) the average daily morphine milligram equivalent (MME) prescribed to those patients.

Exclusions to this methodology include (1) beneficiaries who have cancer or sickle cell disease diagnosis, are enrolled in hospice, or reside in a long-term care facility; and (2) providers subject to a current CMS or HHS Office of Inspector General (“HHS–OIG”) investigation. Over time, should the opioid crisis continue to evolve and CDC practice guidelines change, we will make further adjustments to the methodology, as appropriate, to ensure beneficiary safety, as well as alignment with clinical standards and regulatory requirements that govern the Medicare Part D program. Our current outlier prescriber methodology is available on the CMS website (<https://www.cms.gov/files/document/methodology-comparison.pdf>), and any future updates to the methodology will be made at this website location.

Section 6065 of the SUPPORT Act also established additional requirements for outlier prescribers that are identified by us as “persistent” at section 1860D–4(c)(4)(D)(v) of the Act, although it does not provide criteria or thresholds to determine persistently identified outlier prescribers of opioids. First, we may require a persistent outlier to enroll in the Medicare program but only after other appropriate remedies have been provided, such as receiving technical assistance on best practices related to prescribing opioid and non-opioid pain management therapies through entities funded through section 6052 of the SUPPORT Act. Second, we are required to communicate information on such prescribers to Part D plan sponsors no less frequently than annually. Considering the significant implications of being identified as an outlier prescriber of opioids, including a persistent outlier, we believe it prudent to clearly outline the key criteria for such a designation in regulation.

2. Proposed Provisions

First, to reflect the requirements surrounding the Secretary's identification of an outlier prescriber of opioids under section 1860D–4(c)(4)(D)(ii) of the Act, we propose to define an outlier prescriber of opioids as a statistical outlier when compared to their peers based on NPPES taxonomy and state. Second, given the potential impact(s) of being identified as a persistent outlier prescriber of opioids (for example, the potential for becoming a lead for a Part D plan sponsor investigation), we are proposing and seeking public comment on what criteria should apply for designation as a persistent outlier prescriber of opioids. We propose to establish a threshold to identify persistent outlier prescribers of

opioids as those outlier prescribers who receive three consecutive outlier prescriber notifications from CMS based on the same methodology. If there is an update to the methodology, only prescribers that have been identified three times by the same methodology would be considered “persistent.” We seek comments on this threshold.

Specifically, we propose to add a paragraph (f) under § 423.504:

- (f) Outlier Prescribers of Opioids.

++ CMS will identify and send notifications to outlier prescribers of opioids, which includes information about how the prescriber compares to other specified prescribers and resources on proper prescribing methods.

++ At least annually, CMS will communicate information about persistent outlier prescribers of opioids to all Part D plan sponsors.

We also propose to add the following definitions under § 423.4:

Outlier prescriber of opioids means a prescriber who is a statistical outlier compared to their peers in a specialty and geographic area.

Specialty means the National Plan and Provider Enumeration System (NPPES) taxonomy of a prescriber.

Geographic area means the State in which a prescriber is practicing.

Persistent outlier prescriber of opioids means an outlier prescriber identified by CMS in three consecutive outlier prescriber notifications.

F. Reopening and Payment Appeals

The Inflation Reduction Act of 2022 (Pub. L. 117–169) made several amendments to Part D of Title XVIII of the Social Security Act (the Act), including adding section 1860D–14C of the Act, which describes the Manufacturer Discount Program; section 1860D–14D of the Act, which describes the Selected Drug Subsidy Program; and section 1860D–15(h) of the Act, which describes the temporary retrospective subsidy for the reduction in cost-sharing and deductible for adult vaccines recommended by the advisory committee on immunization practices (ACIP) and insulin. The temporary retrospective subsidy for ACIP-recommended adult vaccines and insulin was limited to contract year 2023 and is hereinafter referred to as the Inflation Reduction Act Subsidy Amount (IRASA).

In subregulatory guidance, we described the reconciliation and payment determination processes for the Manufacturer Discount Program, selected drug subsidy, and IRASA.³³ For

the Manufacturer Discount Program and the selected drug subsidy, we make monthly prospective payments for estimated costs submitted with bids, then make final payments based on the a plan’s actual costs after a coverage year after obtaining all of the information necessary to determine the amount of payment through cost-based reconciliations.

IRASA is the difference between the beneficiary cost-sharing for a covered insulin product or an ACIP-recommended adult vaccine under the plan’s 2023 benefit design and the applicable statutory maximum cost-sharing (\$35 for each covered insulin product and \$0 for ACIP-recommended adult vaccines). The difference was reimbursed by Medicare during the 2023 Part D payment reconciliation. We propose to amend § 423.308 to add the definition of Inflation Reduction Act Subsidy Amount (IRASA).

We propose that the Manufacturer Discount Program reconciliation, selected drug subsidy reconciliation, and IRASA reconciliation payment determinations would be payment determinations that may be reopened by CMS under § 423.346 and would also be appealable by the Part D sponsors under § 423.350. Therefore, we propose to update the existing regulation concerning the reopening of final payment determinations and the existing payment appeals regulation by adding the Manufacturer Discount Program reconciliation, selected drug subsidy reconciliation, and IRASA reconciliation payment determinations. We also propose to amend the time for filing a payment appeal under the existing payment appeals provision.

1. Definition of Inflation Reduction Act Subsidy Amount (IRASA)

Section 1860D–2(b)(9) of the Act imposes a \$35 monthly limit on cost sharing for a month’s supply of each covered insulin product throughout all phases of the Part D benefit for CYs 2023, 2024, and 2025. For CY 2026 and each subsequent year, this limit is the lesser of: (1) \$35, (2) an amount equal to 25 percent of the maximum fair price

established for the covered insulin product in accordance with Part E of title XI of the Act; or (3) an amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the Part D Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug (MA–PD) plan. Section 1860D–2(b)(8) of the Act requires the elimination of beneficiary cost sharing for ACIP-recommended adult vaccines that are administered in accordance with the ACIP recommendation (hereafter referred to as “ACIP-recommended adult vaccines”) under a Part D plan throughout the entire Part D benefit beginning January 1, 2023. Section 1860D–15(h) of the Act requires that a temporary retrospective subsidy be paid to Part D plans for the reduction in cost sharing and the elimination of the deductible for ACIP-recommended adult vaccines and covered insulin products during the 2023 plan year—the Inflation Reduction Act Subsidy Amount (IRASA).

We propose to amend § 423.308 to add the definition of Inflation Reduction Act Subsidy Amount (IRASA). Under our proposed rule, Inflation Reduction Act Subsidy Amount (IRASA) would mean a temporary retrospective subsidy paid to Part D plan sponsors for contract year 2023 for the statutory reduction in cost-sharing and deductible for covered insulin products or for advisory committee on immunization practices (ACIP)-recommended adult vaccines administered in accordance with the ACIP recommendation and is equal to the difference between the following: (1) The beneficiary cost-sharing for a covered insulin product or an ACIP-recommended adult vaccine under the plan’s approved bid submitted under § 423.265 for contract year 2023, and (2) the applicable statutory maximum cost-sharing for the covered insulin product or for the ACIP-recommended adult vaccine for contract year 2023.

2. Reopenings

Under the authority under section 1860D–15(f)(1)(B) of the Act, the Secretary has the right to inspect and audit any books and records of a Part D sponsor or MA organization that pertain to the information regarding costs provided to the Secretary. We stated in our final rule, “Medicare Program; Medicare Prescription Drug Benefit,” which appeared in the January 28, 2005 **Federal Register** (70 FR 4194, 4316), that this right to inspect and audit would not be meaningful, if upon finding mistakes under such audits, the Secretary was not able to reopen final payment determinations. Therefore, we

³³ See the HPMS memorandum, *Revised Medicare Part D Manufacturer Discount Program Final*

Guidance, December 20, 2024 (available at <https://www.cms.gov/files/document/revise-manufacturer-discount-programfinal-guidance122024.pdf>); Final CY 2026 Part D Redesign Program Instructions (available at <https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf>); and HPMS memorandum, *PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023*, September 26, 2022 (available <https://www.cms.gov/files/document/2023-pde-reporting-instructions.pdf>).

established the reopening provision at § 423.346, which allows CMS, at its discretion, to reopen and revise initial or reconsidered specified payment determinations. Paragraph (a) of § 423.346 lists the payment determinations that we may reopen and revise. These payment determinations include the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low-income subsidy described in § 423.329(d), and final risk corridor payments as described in § 423.336. In our final rule, “Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” which appeared in the February 12, 2015 **Federal Register** (80 FR 7912, 7936), we added the Coverage Gap Discount Program reconciliation payment to the list of payment determinations that we may reopen and revise.

We propose to amend § 423.346(a) to add the Manufacturer Discount Program reconciliation payment determination, the selected drug subsidy reconciliation payment determination, and the IRASA reconciliation payment determination to the list of payment determinations that we may reopen and revise. Under our proposal, these payment determinations would be subject to reopening consistent with the current reopening guidelines described at § 423.346, which are explained in detail in our final rule, “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE),” which appeared in the April 23, 2024 **Federal Register** (89 FR 30448, 30460) (hereinafter referred to as the Contract Year 2025 Final Rule).

Under our proposal, the selected drug subsidy reconciliation payment determination and the IRASA reconciliation payment determination would be included in scheduled global reopenings and could be included in targeted reopenings, which are defined at § 423.308 (definition of *Reopening*). However, similar to the Coverage Gap Discount Program reconciliation payment determination, we anticipate that we would rarely reopen the Manufacturer Discount Program reconciliation payment determination. This is because Manufacturer Discount

Program invoicing continues after the Manufacturer Discount Program reconciliation, and sponsors receive payments from the pharmaceutical manufacturers for a total of 17 quarters.³⁴ Under our proposal and similar to current guidance in the CY 2025 Final Rule, we would also be able to reopen and revise the Manufacturer Discount Program reconciliation, selected drug subsidy reconciliation, and the IRASA reconciliation payment determinations, as necessary, to correct certain issues such as a CMS-identified problem with an internal CMS file that we used in a payment reconciliation.

3. Payment Appeals

Section 1860D–15(d)(1) of the Act gives the Secretary broad authority to develop payment methodologies for payments described in section 1860D–15 of the Act, and we use this broad authority to establish a payment appeals process. Accordingly, in our final rule, “Medicare Program; Medicare Prescription Drug Benefit,” which appeared in the January 28, 2005 **Federal Register** (70 FR 4194, 4316), we added § 423.350 to establish a payment appeals process for the reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b); the reconciled reinsurance payments under § 423.343(c); the reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); and the final risk-sharing payments made under § 423.336. In our final rule, “Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” which appeared in the February 12, 2015 **Federal Register** (80 FR 7912, 7938), we added the reconciled Coverage Gap Discount Program payment to the list of payment determinations that could be appealed under § 423.350.

We propose to amend § 423.350(a)(1) to add the following payment determinations that would be subject to appeal under § 423.350—the reconciled IRASA payment for contract year 2023, reconciled Manufacturer Discount Program payment, and reconciled selected drug subsidy payment. We note that the IRASA reconciliation payment for contract year 2023 has already been made to Part D sponsors. In

subregulatory guidance, we explained that the Part D sponsors could appeal the IRASA reconciliation payment determination.³⁵ We propose to include the IRASA reconciliation payment determination in the appeals provision for consistency with the proposed updates to § 423.346, under which we would be able to reopen the IRASA reconciliation payment determination. Indeed, we anticipate that we would reopen the IRASA reconciliation during the global reopening of the contract year 2023 Part D payment reconciliation. Under our proposal, the reopened IRASA reconciliation payment determination would be appealable under § 423.350.

The Part D payment appeals process only applies to perceived errors in the application of our payment methodology. The payment information submitted by the Part D sponsor cannot be appealed through this process. Part D sponsors are expected to submit payment information correctly and within the established timeframes. We codified at § 423.350(a)(2) that payment information submitted to us under § 423.322 and reconciled under the various payment provisions is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations. We propose to amend the regulation at § 423.350(a)(2) to add language specifying that information that is submitted and reconciled or used in the payment calculations for the Manufacturer Discount Program reconciliation, the selected drug subsidy reconciliation, and the IRASA reconciliation are final and would not be appealable nor would the appeals process be used to submit new information after the submission of information necessary to determine these retroactive adjustments and reconciliations.

We also propose to amend § 423.350(a)(2) to add a reference to § 423.336, which describes the risk corridor payment, to correct an inadvertent omission. The information that is submitted and used in the payment calculations under § 423.336 is final and would not be appealable nor would the appeals process be used to submit new information after the

³⁴ See the *Medicare Part D Coverage Gap Discount Program (CGDP) and Manufacturer Discount Program (MDP) Calendar*, available at [https://tpadadministrator.com/internet/tpaw3/files.nsf/F/TPACGDP_MDP_Calendar_2024-2028_12062024.pdf/\\$FILE/CGDP_MDP_Calendar_2024-2028_12062024.pdf](https://tpadadministrator.com/internet/tpaw3/files.nsf/F/TPACGDP_MDP_Calendar_2024-2028_12062024.pdf/$FILE/CGDP_MDP_Calendar_2024-2028_12062024.pdf).

³⁵ HPMS memorandum, *Completion of the 2023 Final Part D Payment Reconciliation and the 2023 Inflation Reduction Act Subsidy Amount (IRASA) Reconciliation*, September 27, 2024 (available at <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-23-27>).

submission of information necessary to determine that payment determination.

4. Payment Appeals—Time for Filing

Under existing § 423.350(b)(1), the payment appeal (specifically, the request for reconsideration of the payment determination) must be filed within 15 days from the date of the final payment. We propose two amendments to § 423.350(b)(1) to reflect actual practice. First, we propose to amend 15 days to 15 calendar days. Second, we propose that the appeal deadline would be based on the release of the reconciliation reports to the Part D sponsors, as opposed to the date of the final payment. The reconciliation reports that CMS releases to the Part D sponsors are detailed reports that specify the inputs and results of the payment reconciliation at the plan-level. These detailed reports allow plans to understand how their Part D payment reconciliation was calculated by us. Part D sponsors currently appeal their payment determinations based on information in the reconciliation reports. Therefore, we propose to update that the time for filing an appeal would be within 15 calendar days from the date we issue the payment reconciliation report for the payment determination that is being appealed by the Part D sponsor.

The proposals described in this section of the final rule are consistent with our current guidance and requirements. The proposed changes are updates that do not place additional requirements on Part D sponsors, nor do the proposed changes place any additional burden on the Part D sponsors or their pharmacy benefit managers (PBMs).

Part D sponsors' compliance with this reopening process is evidenced by each Part D sponsor's signed attestation certifying the cost data (under § 423.505(k)(3) and (5)) that we use in each of the reopenings. In addition, the burden associated with the submission of cost data is already approved under the OMB control numbers 0938–0982 (CMS–10174) and 0938–0964 (CMS–10141).

We believe that the payment appeals process at § 423.350 is an administrative action or investigation with respect to a specific party, which is exempt from the COI process. Therefore, as our changes do not result in additional burden, we have not included a discussion of this provision in the COI section of this rule.

We are not scoring this provision in the Regulatory Impact Analysis section because industry is already complying with this process.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. *Revise List of Non-Allowable Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)*

The “Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule” appeared in the April 15, 2025, **Federal Register** (90 FR 15792), hereafter referred to as the April 2025 final rule. In this rule, CMS codified new regulation language at 42 CFR 422.102(f)(1)(iii)(G) that cannabis products are not allowable Special Supplemental Benefits for the Chronically Ill (SSBCI), as they are illegal substances under federal law.

Section 10113 of the Agriculture Improvement Act of 2018, also known as the 2018 Farm Bill (Pub. L. 115–334,³⁶) added a definition of “hemp” to the Agricultural Marketing Act of 1946. Under this definition, “[t]he term ‘hemp’ means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.” In addition, section 12619 of the 2018 Farm Bill amended the Controlled Substances Act (CSA) to exclude hemp from the CSA’s definition of marijuana.³⁷ The Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026, amends the definition of hemp to exclude any cannabinoids that are not naturally found or produced in the cannabis plant, cannabinoids that are synthesized outside of the plant, and final form products for human use that contain more than 0.4 milligrams per container combined total of naturally occurring tetrahydrocannabinols and other naturally produced cannabinoids determined by the Secretary of Health and Human Services to have the same effect. This amended definition of hemp takes effect on November 12th, 2026. Consequently, hemp and hemp-derived

cannabis products that meet the current 2018 definition are not federally controlled substances through November 11th, 2026, and those that meet the amended definition beginning on November 12th, 2026, will remain not federally controlled substances as of that date. If such products comply with all other applicable federal laws, including any future changes to the definition of hemp and applicable provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), then they are not illegal under federal law. To reflect this distinction, CMS proposes amending § 422.102(f)(1)(iii)(G) to state more precisely that cannabis products that are illegal under applicable State or Federal law, including the FFDCA, are not allowable as SSBCI.

Currently, only one product that meets the definition of hemp under the 2018 Farm Bill has been approved as a drug in the United States: the prescription drug Epidiolex. CMS notes that Epidiolex has been approved by the FDA to treat seizures and is covered under Medicare Part D, so it would not be permitted to be offered as a Part C supplemental benefit. In addition, in December 2018, FDA completed its evaluation of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil.³⁸ FDA had no questions at that time about the notifier’s conclusion that the ingredients were GRAS for their intended use in food. An ingredient that meets the GRAS standard can be used in food without being required to undergo premarket review and approval by FDA for that intended use.³⁹

Therefore, this proposal would allow MA organizations to offer hulled hemp seed, hemp seed protein powder, and hemp seed oil, consistent with FDA’s review of the GRAS notices,—as SSBCI to qualifying enrollees, to the extent otherwise appropriate as SSBCI and under federal and applicable state law. Additionally, at this time, any cannabis product with a delta-9 THC content above the 0.3 percent threshold is still considered marijuana, remains a Schedule I controlled substance, and therefore is illegal under federal law and would be subject to CMS’s prohibition. Any product that does not comply with the amended definition of hemp after the November 12th, 2026, effective date will be a Schedule I controlled

³⁶ Agriculture Improvement Act of 2018, H.R.2, 115th Congress (2018). <https://www.congress.gov/bills/115/congress/house/bill/2>.

³⁷ <https://www.congress.gov/crs-product/R44742#:~:text=The%202018%20farm%20bill%20further,regulations%2C%20and%20applicable%20state%20regulations.>

³⁸ <https://www.fda.gov/food/hfp-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food>.

³⁹ <https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras>.

substance as of that date, and therefore will be illegal under federal law⁴⁰ and subject to CMS's prohibition.

Section 1852(a)(3)(D)(ii)(I) of the Act requires that an item or service offered as an SSBCI must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. There may be situations in which foods containing one or more of these three specific ingredients meet the "reasonable expectation of improving or maintaining the health or overall function" standard for SSBCI. For example, there is evidence that hemp seed protein powder may offer nutritional benefits.⁴¹ CMS reminds MA organizations about the importance of ensuring that the items and services provided to enrollees, including any foods containing these specific hemp-derived ingredients, meet the requirements for being offered as an SSBCI. CMS notes that if this proposal is finalized and MA organizations choose to offer any of these three hemp-derived ingredients, they would be subject to all applicable SSBCI requirements under § 422.102(f), including the bibliography requirements for SSBCI items and services set forth at 42 CFR 422.102(f)(3) to demonstrate through relevant acceptable evidence that the item has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee.

The proposed amended language also clarifies that MA organizations remain prohibited from covering any cannabis product, including any hemp-derived cannabis product, that is illegal under state law within their service area regardless of the product's federal legal status.

While this proposal would modify existing policy, it is not expected to have an impact on current operating expenses for MA organizations as the proposal would not impose any new burden or collection of information requirements.

CMS seeks comments on all aspects of this proposal and may consider revisions to the final policy based on the comments received.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies (Operational Changes)

A. Special Enrollment Period for Provider Terminations (§ 422.62(b)(23))

In the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program Final Rule (85 FR 33796) we codified at § 422.62(b)(23) the special election period (SEP) for Significant Change in Provider Network. Currently, when CMS determines a change in a plan's provider network to be significant, affected enrollees are eligible for this SEP and may use it to request enrollment in another MA plan or to disenroll to original Medicare from the MA plan that has changed its network. As described in § 422.62(b)(23)(ii), enrollees are "affected" by a significant network change and eligible for this SEP when they are assigned to, are currently receiving care from, or have received care within the past three months from a provider or facility being terminated from the MA (or MA-PD) plan's provider network.

Changes to provider networks occur routinely throughout the year; individual clinicians may relocate their practice, retire or expire over the course of the year. For the discussion that follows, we wish to distinguish these routine, smaller scale, changes in provider networks from the more substantial changes, such as a large medical group or hospital system leaving the network. CMS requires that MA organizations notify enrollees of changes in a provider network resulting from the termination—with or without cause—of a contract with a provider organization pursuant to §§ 422.111(e) and 422.2267(e)(12). This notification requirement is separate from, and therefore not impacted by, the question of whether CMS would consider the network change to be significant for purposes of the SEP described in § 422.62(b)(23). Further, it is longstanding CMS policy that MA plan enrollees who believe they may be adversely impacted by a provider termination may contact 1–800–MEDICARE to request an SEP due to exceptional circumstances, such as situations where access to services is compromised and adverse health consequences may result, including interruptions in treatment. CMS reviews the supporting details and documentation for these requests and determines eligibility for an exceptional

circumstances SEP on a case-by-case basis.

Historically, the types of provider network changes that have been more likely to convey eligibility for the SEP for Significant Change in Provider Network are those that go beyond individual or limited provider terminations that occur during the routine course of plan operations or have the potential to substantially impact a large number of the MA organization's enrollees, such as terminated relationships with multispecialty group practices or hospital systems. MA organizations notify CMS of any no-cause provider termination that the MA organization deems to be a significant provider termination at least 90 days prior to the effective date. After receiving such notification, CMS implements an internal review process that evaluates the totality of the circumstances around each termination to determine whether the change in provider network is significant. The timeframe for CMS determinations of a significant network change varies depending on the circumstances of each case. If CMS determines that a provider termination represents a significant change in the plan's provider network, the CMS Account Manager for the MA organization notifies the organization of the CMS determination and of the requirement to issue written notification to affected enrollees of their eligibility for an SEP, the start and end dates of the SEP, how to make use of the SEP and also Medigap guaranteed issue (GI) rights in accordance with § 422.62(b)(23)(iii) and Section 1882(s)(3)(D) of the Act. CMS provides model language regarding the SEP and Medigap GI rights for the MA organization to use in its notice to affected enrollees.⁴² Currently, the requirement for written notification to enrollees regarding their eligibility for the SEP for Significant Change in Provider Network (§ 422.62(b)(23)(iii)) is separate and distinct from the requirement that MA organizations provide enrollees advance notice of routine provider terminations (§§ 422.111(e) and 422.2267(e)(12)).

Although CMS evaluates cases of possible significant network change carefully and strives to reach a determination as expeditiously as possible, we continue to look for ways to reduce the time it takes to inform beneficiaries of their rights and their enrollment options. Specifically, we are looking to streamline the currently

⁴⁰ Under the Controlled Substances Act, Schedule I controlled substances may only be used for research purposes by practitioners who are registered with DEA to conduct such research. 21 U.S.C. 822(b), 823(g)(2).

⁴¹ <https://www.sciencedirect.com/science/article/pii/S221345302200235X>.

⁴² Medicare Advantage Enrollment and Disenrollment Guidance Appendices and Exhibits.

separate notification requirements for provider terminations and the SEP for Significant Change in Provider Network. Accordingly, we are proposing several enhancements to the current process by which an MA enrollee is provided the option to change plans when one or more of their plan providers are leaving the plan's network.

Specifically, at § 422.62(b)(23) we propose to change the eligibility criteria for the current SEP for Significant Change in Provider Network to reflect that a determination of significant provider network change by CMS or an MA organization is not necessary for an enrollee who is affected by the provider network change to be eligible for the SEP. As noted, it is longstanding CMS policy that MA plan enrollees who believe they may be adversely impacted by any provider termination, significant or otherwise, may contact 1-800-MEDICARE to request an SEP due to exceptional circumstances. We propose to retain the definition of an "affected enrollee" as an enrollee who is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated. As is the case for the current SEP for Significant Change in Provider Network, the revised SEP, which we propose to name the SEP for Provider Terminations, would begin the month the individual is notified of eligibility for the SEP and would continue for an additional 2 calendar months after the month in which the enrollee is notified of the SEP.

While we are not proposing any changes to the provider termination notification timeliness requirements at § 422.111(e), we believe that it is in the best interests of both the MA organization and the enrollee for this SEP information to be included in the provider termination notice for affected enrollees, rather than require the MA organization to issue a separate notice, as is most often the case currently when CMS determines a network change to be significant. Accordingly, at § 422.2267(e)(12)(ii)(D), we are proposing that the following information, currently provided to enrollees affected by a network change determined by CMS to be significant, be included in the provider termination notice.

- Information about the Annual Coordinated Election Period (AEP) and the MA Open Enrollment Period (MA-OEP);
- Notification that the affected enrollee is eligible for a special election period (SEP), as specified in § 422.62(b)(23), including the start and end dates of the SEP;

- Medigap guaranteed issue (GI) rights; and
- A note stating that individuals who have coverage through an employer or union should contact their benefits administrator before leaving their current MA plan to find out how making such a change may affect their employer or union health benefits.

Requirements related to the model MA Provider Termination Notice content are codified at § 422.2267(e)(12); we propose to revise § 422.2267(e)(12)(ii)(D) to require that the information described above be included in the notice.

Consistent with the current SEP for Significant Change in Provider Network, the proposed SEP for Provider Terminations could be used by an affected enrollee only once per provider network change. MA organizations would be able to determine eligibility for the proposed SEP for Provider Terminations based on beneficiary attestations of election period eligibility, such that beneficiaries would not be limited to requesting enrollment via 1-800-MEDICARE. An individual would be able to attest directly to the plan that they were affected by a provider termination.

In the final rule in which we codified the SEP for Significant Change in Provider Network (85 FR 33796) we also codified the SEP to enroll in a PDP for MA enrollees using the SEP provided in CMS's regulations at 42 CFR 422.62(b)(23) to disenroll from an MA plan. We are not proposing any changes to the eligibility criteria for § 423.38(c)(30), meaning that this coordinating Part D SEP, codified at § 423.38(c)(30), will continue to allow MA enrollees to request enrollment in a PDP if and when they use the SEP at § 422.62(b)(23) to disenroll from an MA plan.

CMS data suggests that use of the current SEP for Significant Change in Provider Network by eligible beneficiaries is low. In 2024, of the MA enrollees who were notified that they were eligible for the SEP and could switch to another MA plan or disenroll from MA to original Medicare, approximately 3.6 percent made an election of any type. Thus, our experience shows that when enrollees are affected by a provider termination and notified that they are eligible for a SEP to change plans or switch to Original Medicare, presumably to follow their provider, very few actually use the SEP. This leads us to conclude that other factors, such as formulary, benefits, plan premium, cost sharing, familiarity, and other plan attributes may play a role in the affected enrollee's

decision and may result in the enrollee choosing not to leave their current plan.

We anticipate a one-time burden on MA organizations to update their existing written provider termination notice in compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii). We conclude that the proposed changes to the regulatory text will not have any impact on the Medicare Trust Funds. All information impacts related to the procedural steps plans must take to determine eligibility for an election period have already been accounted for under OMB control number 0938-0753 (CMS-R-267).

B. Coordination of Election Mechanisms for MA and Part D (§§ 422.62, 422.66, 423.32, 423.36, and 423.38)

Section 1851(c) of the Act provides the Secretary with the authority to establish a process by which MA enrollment elections (hereinafter referred to as "elections") are made and changed, including the form and manner in which they are changed. Section 1851(e)(4)(D) of the Act provides the Secretary with the authority to establish Special Election Periods for exceptional conditions, during which individuals may make elections. Section 1860D-1(b)(1)(B) of the Act directs the Secretary to use rules related to enrollment, disenrollment, termination, and change of enrollment for Part D sponsors that are similar to those established for MA plans under specified subsections of section 1851 of the Act. Section 1860D-1(b)(1)(B)(ii) of the Act specifies that the Secretary shall use section 1851(c) of the Act, other than paragraph (3)(A) and paragraph (4) of such section, for Part D rules relating to exercise of choice.

Consistent with these sections of the Act, in 1998, we published a final rule (63 FR 34968) to codify the Part C election process required under section 1851(c) of the Act at § 422.66. In 2005, we published a final rule (70 FR 4194) to codify the Part D election process required under section 1860D-1(b)(1)(B) of the Act at §§ 423.32 and 423.36. The Parts C and D subpart B regulations set forth our requirements with respect to the election process under §§ 422.60 (election process), 422.66 (coordination of enrollment and disenrollment through MA organizations), 423.32 (enrollment process), and 423.36 (disenrollment process).

MA election requests, with few exceptions, are submitted by the individual requesting enrollment in or disenrollment from a particular MA plan. In certain circumstances, namely passive enrollment (a process where

CMS initiates enrollment into another plan in cases of immediate plan terminations, harm to beneficiaries, or for the promotion of integrated care with state Medicaid agency approval) and default enrollment (a process available only for integrated D–SNP enrollments), CMS directly enrolls individuals and transmits an enrollment transaction to the plan, which bypasses the usual process discussed later in this section.

Current Part C regulations at § 422.60(e) specify that MA organizations must have effective systems for receiving, controlling, and processing election requests. After satisfying those requirements and accepting an individual's election request, the MA organization transmits the information necessary for CMS to add the individual to its records as an enrollee of the MA organization. Current Part C regulations at §§ 422.66(a) and (b) specify that elections may be made by filing appropriate election forms with the MA organization or through other mechanisms as determined by CMS. The same process is mirrored in current Part D regulations at §§ 423.32(a) through (d) and 423.36(a) and (b), whereby the Part D sponsor receives an election request from an individual and then submits necessary information to CMS.

Outside of circumstances where CMS directly enrolls an individual into a plan (passive, default enrollment, etc.) most election requests are filed with the MA organization or Part D sponsor, though the election form or mechanism may differ. Election mechanisms are how an individual communicates their election request to the MA organization or Part D sponsor, whether on paper, over the phone, electronically, etc. Even if an individual uses a CMS-operated election mechanism (1–800–MEDICARE or the Online Enrollment Center), the election request is still filed with the plan for processing.

Historically, CMS has regulated the required content of election mechanisms under the “form and manner” authority specified at section 1851(c)(1) of the Act and codified at §§ 422.60(c), 422.66(a), 423.32(a), and 423.36(a). Consistent with section 1851(e)(4) of the Act, CMS has required CMS approval for certain election periods. For example, consistent with the provisions in section 1851(e)(4)(C) providing that a SEP may be available where an “individual demonstrates (in accordance with guidelines established by the Secretary) that . . . the organization offering the plan substantially violated a material provision of the organization's contract

under this part in relation to the individual . . . ,” CMS's current regulations governing the special enrollment period (SEP) for contract violation (§§ 422.62(b)(3) and 423.38(c)(8)) provides that the SEP is available where an individual demonstrates to CMS that specified criteria have been met. This SEP is only available once CMS determines that a contract violation has occurred. An individual alleging a contract violation must call 1–800–MEDICARE to explain their circumstances and demonstrate to CMS that there was a violation. Once eligibility is demonstrated, the individual can elect a new plan or disenroll from their current plan and the election request is subsequently transmitted to the plan to process. The requirement that the individual demonstrate eligibility to CMS has been in place since the SEP was first codified in a 1998 final rule (63 FR 34968, 34980) and the process to demonstrate eligibility to CMS is also described in section 30.6.28 of the Medicare Advantage and Part D Enrollment and Disenrollment Guidance, *see also* MA–PD Plan Communications User Guide, pg. 3–38.

There are other SEPs that are currently only available with prior CMS approval, provided by CMS sending a notice or election request to the MA organization or Part D sponsor. These SEPs are: SEP for individuals who disenroll in connection with CMS sanction (§§ 422.62(b)(5) and 423.38(c)(12)); SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage (§§ 422.62(b)(20) and 423.38(c)(2)); and SEP for other exceptional circumstances (§§ 422.62(b)(27) and 423.38(c)(36)). As described in CMS's Medicare Advantage and Part D Enrollment and Disenrollment Guidance, Section 30.6, in order for CMS to review that appropriate circumstances apply to allow for an SEP based on a CMS sanction, an individual not receiving adequate information about loss of creditable prescription drug coverage, or other exceptional circumstances, plans must have prior approval from CMS to submit enrollment transactions based on these SEPs.

We are proposing to codify our current policy that for elections that are made based on certain special election periods, the beneficiary at issue must either have CMS approval for the use of that SEP through the use of a CMS-operated election mechanism (for example, 1–800–MEDICARE or the Online Enrollment Center (OEC)) or other means, such as enrollee receipt of a notice. We propose this change to

codify longstanding guidance and practice requiring CMS approval for certain SEPs. This policy allows for control over election periods and mechanisms to ensure appropriate use and allows us to delineate a clear process for each election. To accomplish this, we would propose to establish at §§ 422.66(g), 423.32(k), and 423.36(g) the requirement that elections may require CMS approval based on the use of specified SEPs. CMS approval would be provided for plan elections either through the use of a CMS-operated election mechanism or through the individual's receipt of a notice which explains eligibility for the SEP and election instructions. As CMS approval would be an eligibility criterion of the SEP, MA organizations and Part D plan sponsors may not transmit elections to CMS using the specified SEPs without prior CMS approval.

Under this proposal, we would codify these limitations for the following SEPs:

- SEP for individuals who disenroll in connection with CMS sanction (§§ 422.62(b)(5) and 423.38(c)(12));
- SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage (§§ 422.62(b)(20) and 423.38(c)(2));
- SEP for contract violation (§§ 422.62(b)(3) and 423.38(c)(8));
- SEP for other exceptional circumstances (§§ 422.62(b)(27) and 423.38(c)(36)).

These limitations would be codified at §§ 422.62(b)(3), (b)(5), (b)(20), (b)(27), and 423.38(c)(2), (c)(8), (c)(12), and (c)(36). Language would be added to each SEP we propose to limit to require CMS approval. The language would indicate that CMS approval is required and reference how CMS approval would be indicated, either through providing a notice or the acceptance of an election through a CMS-operated mechanism. These limitations and applicable SEPs are also described at §§ 422.66(g)(2), 423.32(k)(2), and 423.36(g)(2).

We are proposing to codify these limitations in order to better oversee the use of SEPs which may not be appropriate for plans to use without prior CMS eligibility determination and approval. It would, for example, be inappropriate for an organization to evaluate the claim that another organization violated their contract with an individual, or that the individual was impacted by conduct that was sanctioned by CMS. In those cases, other organizations are not neutral arbiters of eligibility as they have a financial interest in deeming the conduct of other organizations as a contract violation or they lack the complete information about the

circumstances of the sanctioned conduct. The SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage is similarly justified as requiring CMS approval prior to the election request being filed with the plan for processing. The eligibility determination for this SEP also requires evaluation of the conduct of another organization or entity and whether they provided adequate notice of the loss of creditable coverage. We believe these SEP limitations would prevent organizations, who do not have appropriate context, from incorrectly determining eligibility. This is especially true for the SEP for other exceptional circumstances, which covers situations not otherwise captured in the SEPs in regulation. This SEP is determined on a case-by-case basis for circumstances that warrant an enrollment opportunity given the exceptional conditions experienced by the individual. In these types of cases, only CMS can appropriately consider the circumstances of an individual's eligibility.

In order to best facilitate CMS approval prior to the election request being filed with the plan, these SEPs should only be available through a CMS-operated mechanism, to allow the approval for the SEP to be sent to the plan along with the election request for processing. The requirement for certain SEPs to be approved by CMS first, before the election is filed with the plan, does not preclude the involvement of an agent or broker assisting the enrollee. The enrollee can meet with an agent/broker for assistance in selecting the best plan for the enrollee. The enrollee can then use the CMS mechanism, for example, call 1-800-MEDICARE on their own or with the assistance of the agent/broker. 1-800-MEDICARE and the OEC are capable of capturing the involvement of the agent/broker and transmitting that information to the newly selected plan when CMS sends the approved election request.

As the pre-existing limitations have been long-standing, previously implemented and are currently being followed by plan sponsors, we conclude that the proposed changes to the regulatory text will not adversely impact plan sponsors, individuals, or agents/brokers, nor would the proposed changes have any impact on the Medicare Trust Funds or result in a paperwork burden. All information impacts related to the procedural steps plans must take to receive and process election requests have already been accounted for under OMB control numbers 0938-0753 (CMS-R-267) for

Part C and 0938-0964 (CMS-10141) for Part D.

CMS welcomes comments on this proposal as well as comments on how these SEPs can be further improved for beneficiaries.

C. Use and Release of Risk Adjustment Data

Section 1853(a) of the Act requires CMS to risk adjust payments made to Medicare Advantage (MA) organizations. In order to carry out risk adjustment, section 1853(a)(3)(B) of the Act requires MA organizations to submit data regarding inpatient hospital services and data regarding other services and other information the Secretary deems necessary. Risk adjustment data are the data submitted to CMS by MA organizations to carry out risk adjustment, including the development and application of a risk adjustment payment model. Regulations at 42 CFR 422.310 establish requirements regarding the collection and submission of risk adjustment data, as well as the allowable uses of risk adjustment data and conditions under which the data can be released.

The MA program now comprises 51 percent of the Medicare population, and there has been a coinciding increase in the number and variety of requests that CMS receives for risk adjustment data. This increase is due to both the utility of the more detailed risk adjustment data that CMS started collecting in 2012 (that is, encounter data) and growing enrollment in MA. With the increased variety of requests for risk adjustment data and CMS's better understanding of the data requests received, CMS has come to recognize that the limits on the use and release of risk adjustment data imposed by § 422.310(f) may be unnecessary, burdensome, and overly restrictive for CMS, and for private and public stakeholders requesting the data. The existing restrictions may limit innovative uses of the data by CMS and non-CMS entities that may improve program integrity, increase efficiency, or reduce waste. The proposal described later in this section would lead to more efficient use of public and private sector resources by removing the existing restrictions on the use and release of risk adjustment data while maintaining the protections in place for beneficiary identifying information through CMS data sharing procedures and for plan-submitted dollar amounts reported for an associated encounter. CMS believes that easing the use and release requirements for risk adjustment data would support the goals of Executive Order 14243 "Stopping Waste, Fraud, and Abuse by Eliminating Information

Silos" (March 20, 2025) by reducing barriers to sharing government data across agencies, improve CMS's ability to effectively and efficiently administer and oversee MA and other Federal health care programs, as well as encourage research into improving health care delivery.

1. Background

Section 1853(a) of the Act requires the Secretary to make monthly payments to MA organizations for each beneficiary enrolled in an MA plan. Section 1853(a)(1)(C) of the Act requires the Secretary to adjust the monthly payments based on risk factors of a plan's enrolled beneficiaries, such as demographic factors and other factors that the Secretary determines are appropriate, including health status. To support risk adjustment, section 1853(a)(3)(B) of the Act requires MA organizations to submit data regarding the services provided to enrollees and other information the Secretary deems necessary.

The requirements for the submission of risk adjustment data by MA organizations are set forth at § 422.310. In accordance with these regulations, MA organizations must submit the data necessary to characterize the context and purposes of each item and service provided to their enrollees by a provider, supplier, physician, or other practitioner in accordance with CMS instruction. Paragraphs (a) through (d) of § 422.310 define risk adjustment data, the basic rules of risk adjustment data collection, the sources and extent of risk adjustment data, and other risk adjustment data requirements. There are two forms of risk adjustment data: (1) data equivalent to Medicare fee-for-service (FFS) data, when appropriate, and to all relevant national standards, referred to as encounter data, and (2) data submitted by MA organizations prior to 2022 in an abbreviated format, referred to as Risk Adjustment Processing System (RAPS) data.^{43 44} Both encounter data and RAPS data submissions include beneficiary diagnoses.

Though section 1853(a)(3)(B) of the Act does not limit the Secretary's use or disclosure of risk adjustment data, Federal laws, such as the Privacy Act of 1974 (as amended), impose restrictions on the disclosure of data collected by Federal agencies, and section 1106(a) of the Act [42 U.S.C. 1306(a)] generally

⁴³ Refer to the CSSC Operations website for information about the submission of encounter data and RAPS data.

⁴⁴ RAPS remains available to MA organizations for the submission of data corrections for years prior to 2022.

prohibits the disclosure of any information obtained by HHS except as the Secretary may prescribe by regulations and except as otherwise provided by Federal law. Over time, CMS has regulated the scope of permissible uses and releases of the MA risk adjustment data, including RAPS and encounter data, in order to achieve a balance between protection of beneficiary identifying information and the interests of MA organizations with the need to effectively administer Federal programs and to encourage research into better ways to provide health care. In the final rule establishing the MA program, published in January 2005 (70 FR 4661), CMS adopted regulations at § 422.310(f) such that CMS may use risk adjustment data to determine the risk adjustment factor used to adjust payments, and for unspecified other purposes, with an exception made to limit CMS's use of medical record data collected under § 422.310(e) to validation studies.

In April 2008, CMS proposed to amend § 422.310 to provide that CMS will collect data from MA organizations regarding each item and service provided to an MA plan enrollee,⁴⁵ which would allow CMS to include utilization data and other factors in developing CMS-Hierarchical Condition Categories (CMS-HCC) risk adjustment models that reflect patterns of diagnoses and expenditures in the MA program. In response to the April 2008 proposal and CMS's efforts to collect encounter data, some stakeholders raised concerns that the use of risk adjustment data for "other purposes," as finalized in the January 2005 final rule, was too broad. Some stakeholders also believed that the data collected for risk adjustment, including encounter data, could not be used for purposes other than risk adjustment. CMS disagreed with this assertion. As stated in the August 2008 final rule, "Section 1853(a)(3)(B) of the Act obligates MA organizations to submit inpatient and outpatient encounter data for purposes of use in implementing a risk adjustment methodology. Unlike the case of information collected under section 1860D–15 of the Act, however, which the statute restricts to being used solely for purposes of implementing that section (see section 1860D–15(d)(2)(B) and (f)(2) of the Act), section 1853(a)(3)(B) of the Act does not impose any such restrictions on other legitimate

uses of the encounter data collected" (73 FR 48653). While CMS is not subject to specific statutory restrictions on our own use of risk adjustment data, the agency responded to industry concerns by establishing in regulation limits on the agency's use of risk adjustment data. Specifically, in the August 2008 final rule, CMS revised § 422.310(f) to establish the following five specific uses of risk adjustment data: (i) calculating the risk adjustment factors used to adjust payments, (ii) updating risk adjustment models, (iii) calculating Medicare Disproportionate Share Hospital (DSH) percentages, (iv) conducting quality review and improvement activities, and (v) for Medicare coverage purposes (73 FR 48651, 48653–48654).

CMS made further revisions to § 422.310(f) in the August 2014 final rule to strengthen program management and increase transparency in the MA program by adding four more uses of risk adjustment data at § 422.310(f)(1)(vi) through § 422.310(f)(1)(ix) and by adding two subparagraphs § 422.310(f)(2) and § 422.310(f)(3) to address the terms under which risk adjustment data could be released to non-CMS entities (79 FR 50324–50334). Specifically, the four uses added to § 422.310(f)(1) in the August 2014 final rule are: (vi) to conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research; (vii) for activities to support the administration of the Medicare program; (viii) for activities conducted to support program integrity; and (ix) for purposes authorized by other applicable laws.

The subparagraph CMS added in the August 2014 final rule at § 422.310(f)(2) provided that the agency may release the minimum data it determines is necessary for one of the purposes listed in § 422.310(f)(1) to other HHS agencies, other Federal executive branch agencies, States, and external entities where that disclosure would be in accordance with: (i) applicable Federal laws; (ii) CMS data sharing procedures; (iii) subject to the protection of beneficiary identifier elements and beneficiary confidentiality, (iv) subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data; and (v) risk adjustment data other than that described in paragraphs (f)(2)(iii) and (f)(2)(iv) of § 422.310 will be released without the redaction or aggregation described in paragraphs (f)(2)(iii) and (f)(2)(iv), respectively. CMS clarified that an external entity could be an

individual, a group, or an organization, and that CMS would not release payment data (that is, dollar amounts) submitted by MA organizations at the level of the encounter as that data might reveal proprietary negotiated payment rates between MA plans and providers (79 FR 50328).

The subparagraph CMS added at (f)(3) in the August 2014 final rule stipulates additional conditions related to the timing of release of risk adjustment data in response to comments from some stakeholders that there should be a delay in releasing the data. CMS added subparagraph (f)(3) in response to comments to clarify that CMS did not plan to regularly release risk adjustment data for a data collection year prior to the completion of the reconciliation period. Risk adjustment reconciliation refers to the period provided to MA organizations to identify and correct errors in data they have submitted for a data collection year to ensure that the risk adjustment data is complete and accurate based on the MA organization's best knowledge, information, and belief. Risk adjustment data are not considered reconciled for a given payment year until after the final risk adjustment data submission deadline, established at § 422.310(g)(2)(ii), which can be no earlier than January 31 of the year following the payment year (for example, January 31, 2025, for payment year 2024). Specifically, § 422.310(f)(3)(i) specifies that risk adjustment data submitted for a given payment year are not available for release by CMS unless the risk adjustment reconciliation has been completed for that payment year except under limited circumstances, such as when CMS determines that releasing risk adjustment data before reconciliation is necessary for emergency preparedness (§ 422.310(f)(3)(ii)) or due to extraordinary circumstances (§ 422.310(f)(3)(iii)) (79 FR 50331).

Since the August 2014 final rule was published, CMS has identified additional circumstances that warranted releasing risk adjustment data prior to reconciliation outside of emergency preparedness and extraordinary circumstances. In the final rule issued in November 2023, CMS provided an additional circumstance (§ 422.310(f)(3)(iv)) to allow for releasing aggregate risk adjustment data prior to risk adjustment reconciliation (88 FR 79397–79400). This provision was added to provide MA utilization data measures on the Care Compare website, along with FFS utilization data, to support the administration of the Medicare program and to more

⁴⁵ Refer to **Federal Register**, 73 FR 23528, section H: <https://www.federalregister.gov/documents/2008/04/30/08-1135/medicare-program-proposed-changes-to-the-hospital-inpatient-prospective-payment-systems-and-fiscal>.

completely fulfill the public reporting required by section 104 of the Medicare Access and CHIP Reauthorization Act (MACRA) and section 10331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act) and provide beneficiaries with useful and appropriate information when selecting a Medicare provider.

The following year, in April 2024, CMS issued a final rule in which CMS revised two of the allowable uses (§ 422.310(f)(1)(vi) and (vii)) to support the administration of the Medicaid program as well as the Medicare program. CMS further allowed for the release of risk adjustment data to State Medicaid agencies before reconciliation for the specific purpose of coordinating care for dually eligible individuals if CMS determined it was necessary and appropriate to support the administration of the Medicare and Medicaid programs (§ 422.310(f)(3)(v)) (89 FR 30536–30541). This expansion of CMS's use of risk adjustment data to support the administration of the Medicaid program is consistent with the goals of better integrating benefits and improving care coordination for dually eligible individuals as established at section 2602 of the Affordable Care Act.

2. Overview of Proposed Regulatory Changes

CMS is proposing to increase access to risk adjustment data while reducing regulatory burden and the resources expended by public and private organizations when requesting risk adjustment data by removing the uses enumerated in § 422.310(f)(1). This change would enable CMS to align more closely with standards applicable to FFS claims and other MA and Part D data and allow the data to be used for more purposes than are permitted under the existing regulations. CMS receives requests to use risk adjustment data for a broad range of purposes including research, health care operations, and oversight of public benefit programs, and from a broad range of entities including academic institutions, government entities, and oversight bodies. CMS believes the limitations imposed by § 422.310(f)(1) may be excessive and does not think that MA risk adjustment data should have a different or more restrictive standard for use and release than the standard applied to Medicare FFS claims. Similarly, the list of external parties to whom the data can be released at § 422.310(f)(2) (“other HHS agencies, other Federal executive branch agencies, States, and external entities”) may unnecessarily limit access to risk

adjustment data to some external entities for legitimate uses that are in the public's interest. CMS believes the proposed removal of § 422.310(f)(2), which would eliminate the restriction on which types of entities can access the data, would be in keeping with our approach to make the risk adjustment data more broadly available. CMS also believes that the provisions on the timing of release of risk adjustment data at § 422.310(f)(3) may be overly restrictive, and there should be more flexibility to release data before reconciliation.

We emphasize, however, that CMS release of the data would remain contingent on Federal law and CMS data sharing procedures, per the proposal at § 422.310(f). CMS data sharing procedures include an evaluation of requests to ensure that data requests comply with applicable Federal laws, regulations, and CMS data policies. Additionally, as part of the request process, unless the requester is a beneficiary requesting his or her own data, a data sharing agreement is established between CMS and the requesters prior to disclosing the data. Data sharing agreements include, but are not limited to, information exchange agreements (IEA),⁴⁶ memoranda of understanding (MOU), and data use agreements (DUAs),⁴⁷ all of which are agreements that document the terms and conditions under which CMS data may be used to ensure that data requesters adhere to CMS privacy and security requirements and data release policies. Included in the terms and conditions are safeguards to protect beneficiary identifying information and confidentiality. Also, consistent with what we stated in the August 2014 final rule, CMS data sharing agreements have enforcement mechanisms, and data requesters are required to acknowledge these mechanisms. For example, penalties under section 1106(a) of the Act [42 U.S.C. 1306(a)], including possible fines or imprisonment, and criminal penalties under the Privacy Act [5 U.S.C. 552a(i)(3)] may apply, as well as criminal penalties imposed under 18 U.S.C. 641 (79 FR 50333). Requesters of CMS data are responsible for abiding by

the law, policies, and restrictions of the data sharing agreements.

Over time, § 422.310(f) has become increasingly complex and cumbersome to implement as CMS receives more requests and identifies additional reasonable uses that CMS did not anticipate. As described previously, CMS has revised the regulation over the years by adding specific uses or exceptions for release of risk adjustment data as they are identified, which is burdensome, slows progress, and limits opportunities to effectively and efficiently administer, oversee, and improve Federal programs, and to conduct health care research that can improve health care delivery. The proposal outlined later in this section would address these concerns by easing restrictions on the use and release of risk adjustment data while maintaining the current protections for plan-submitted payment amounts for an associated encounter that are currently in place. Protections for beneficiary identifying information currently specified in regulation would be maintained through CMS data sharing procedures and other applicable Federal laws as described previously.

CMS expects that transparency in the MA program would be improved by removing: (1) the specific uses at § 422.310(f)(1), aside from protections of the plan-submitted payment amounts that currently exist; (2) the restrictive conditions regarding which external government entities the data can be released to at § 422.310(f)(2); and (3) the timing of when the data can be released at § 422.310(f)(3). We believe these revisions would also allow for more streamlined access to information on the Medicare program as MA grows, thereby strengthening program management, continuing to advance program integrity, supporting public health initiatives, and reducing burden through the implementation of practices and processes for the use and release of MA risk adjustment data that align more closely with standards applicable to other Medicare data, such as FFS claims. The proposed revisions to § 422.310(f) are consistent with Executive Order 14192 “Unleashing Prosperity through Deregulation” (January 31, 2025) by reducing the burden for CMS and external entities associated with the increasingly complex regulation surrounding the use and release of risk adjustment data and would support the goals of Executive Order 14243 “Stopping Waste, Fraud, and Abuse by Eliminating Information Silos” (March 20, 2025) by reducing barriers to sharing government data across agencies.

⁴⁶ Centers for Medicare & Medicaid Services. (n.d.). CMS Information Exchange Agreement (IEA). U.S. Department of Health and Human Services. <https://security.cms.gov/learn/cms-information-exchange-agreement-iea>.

⁴⁷ Centers for Medicare & Medicaid Services. (n.d.). CMS data: Data disclosures and data use agreements (DUAs). U.S. Department of Health and Human Services. <https://www.cms.gov/data-research/cms-data/data-disclosures-and-data-use-agreements-duas>. An example of a research DUA can be found on the ResDAC website at <https://resdac.org/request-form/rif-data-use-agreement>.

3. Proposed Broadening of the Use and Release of Risk Adjustment Data

CMS proposes to ease restrictions on the use of risk adjustment data at § 422.310(f)(1) and repeal the limitations surrounding the release of risk adjustment data at § 422.310(f)(2) and (f)(3), other than the protections currently in place for plan-submitted payment amounts, to allow for the use and release of risk adjustment data that is more aligned with the use and release of FFS claims and other MA data. The limited uses of risk adjustment data were established when CMS resumed activities to collect encounter data to alleviate concerns from some stakeholders that risk adjustment data would be used in ways that they thought were inappropriate. As stated previously, CMS does not believe the statute restricts our use of risk adjustment data, and over time CMS has identified unanticipated uses and releases of the data that are in the public's interest beyond the nine listed at § 422.310(f)(1). Historically, this has necessitated CMS resources to conduct rulemaking to add to or amend the list, resulting in regulatory burden and increasingly complex requirements. For example, as previously discussed, CMS could not use risk adjustment data to conduct evaluations and other analyses to support the Medicaid program, nor could CMS use the data to support the administration of the Medicaid program, like care coordination, before amending § 422.310(f)(1)(vi) and (vii) in the final rule CMS issued in April 2024 (89 FR 30536 through 30541).

Given the growth of MA, risk adjustment data is increasingly important to understanding the Medicare program and health care delivery more broadly. CMS anticipates that the number and variety of requests for risk adjustment data will continue to increase, as will the resources required to enforce the more restrictive requirements and to develop revised regulations when unanticipated yet warranted uses are identified. We believe that removing the specified uses and easing restrictions for data release at § 422.310(f) would provide CMS flexibility to release MA risk adjustment data in a way that more closely aligns with the release of FFS claims and other MA data, which is crucial to burden reduction and the ability of CMS and external entities to be innovative in the pursuit of improved health care delivery and program integrity, greater transparency, and reduced fraud, waste, and abuse.

Specifically, CMS proposes to revise § 422.310(f) as follows: "Regarding the

data described in paragraphs (a) through (d) of this section, CMS may use and release the minimum data it determines is necessary in accordance with CMS data sharing procedures and applicable Federal laws, subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data, unless authorized by other applicable laws." The proposal provides for the stipulation that this proposal does not limit CMS disclosure of data as authorized under separate statutory authority.⁴⁸ We propose to repeal the nine specified uses currently listed in § 422.310(f)(1) that, under the proposal, would be encompassed under the revised (f) text. We also propose to repeal the release restrictions specified at § 422.310(f)(2) and § 422.310(f)(3), other than the existing restrictions on the release of the minimum necessary data and on the release of dollar amounts at the encounter level, which were moved to § 422.310(f). We note, however, that under this proposal, protections to the beneficiary identifying information would be encompassed under the data sharing procedures in the revised (f) text.

Though CMS is proposing to repeal the regulatory language at § 422.310(f)(2) that stipulates protections for beneficiary confidentiality, the protections of beneficiary identifying information currently specified at § 422.310(f)(2) would remain in place in accordance with applicable Federal laws, such as the Privacy Act, section 1106(a) of the Act, and CMS information disclosure regulations at 42 CFR part 401, subpart B, that continue to govern this data sharing. CMS would be able to release an individual's risk adjustment data when authorized by that individual and, for other kinds of requests for release of risk adjustment data, CMS would release such information in accordance with CMS data sharing procedures, consistent with current practice. We intend to continue to protect beneficiary data through, for example, encryption, or removal of the confidential fields when risk adjustment data is released. CMS has an established process to evaluate requests for data and enters into data sharing agreements with data requesters for disclosures of risk adjustment data to ensure that data requesters adhere to CMS privacy and security requirements and data release policies. We believe this process

⁴⁸ For example, 31 U.S.C. 716, 2 U.S.C. 166(d)(1) and 601(d), section 1805 of the Act (42 U.S.C. 1395b–6), section 1128J of the Act (42 U.S.C. 1320a–7k), and section 6(a) of the Inspector General Act of 1978 (5 U.S.C. 406).

contains the necessary checks and safeguards to ensure that the risks of disclosure of beneficiary identifying information are minimal.

CMS is also maintaining the protections that currently exist regarding the release of plan-submitted dollar amounts associated with the items or services submitted to CMS pursuant to § 422.310(b) that characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. In the August 2014 final rule (79 FR 49854), we stated our belief that release of payment data at the level of the encounter record might reveal proprietary negotiated payment rates between MA plans and providers and, therefore, we restricted the release of payment data by only allowing for its release if aggregated. CMS is maintaining the guardrails for payment data (dollar amounts) at the level of the encounter as they were originally finalized in the August 2014 final rule. Per the proposed change to § 422.310(f), CMS may only release aggregated dollar amounts reported for an associated encounter, retaining the regulatory text that currently exists at § 422.310(f)(2)(iv)—risk adjustment data is "subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data." As stated previously, this proposal would not limit CMS disclosure of risk adjustment data as authorized under separate statutory authority.

Currently, § 422.310(f)(3) imposes the restriction that risk adjustment data will not become available for release before reconciliation for the applicable payment year has been completed, unless CMS determines that it is necessary for one of four specific exceptions.⁴⁹ Consistent with our proposed changes to remove the list of permissible uses and conditions for release of risk adjustment data, CMS is also proposing to remove the detailed list of exceptions for release of risk adjustment data prior to reconciliation in paragraph (f)(3). The proposed change would continue to allow for the release of risk adjustment data prior to reconciliation for the four previously identified exceptions and provide flexibility when CMS receives novel requests for data that have not been reconciled.

As discussed previously, because MA plans have a window of time in which they should submit data corrections for a given payment year (typically January

⁴⁹ § 422.310(f)(3)(ii) through (f)(3)(v).

31 of the year following the payment year), risk adjustment data are not considered reconciled for payment purposes before that date has passed. For this reason, there is currently a prohibition against releasing the data prior to the final submission deadline except in specific, limited circumstances. However, over time CMS identified more purposes for which using the data prior to reconciliation may be appropriate and that the original reasons and concerns that led to delaying the release of risk adjustment data in the August 2014 final rule may not always apply or may no longer apply. Some of the purposes identified are reflected in the recent changes to § 422.310(f)(3) where additional exceptions for early release were added, one of which is care coordination, but others may include program integrity initiatives that necessitate timelier data or to support beneficiaries in managing their health by allowing them to access and share their current data. For example, currently, through the CMS Blue Button 2.0 Application Programming Interface (API), an individual may choose to share their own Medicare A, B, and D claims data with Medicare-approved applications or websites that a third party (not Medicare) creates, thereby allowing an individual to use health technology and their own data to improve their health outcomes and decision making. In removing restrictions related to releasing pre-reconciled risk adjustment data, this tool could also be made available to MA enrollees.

While this proposal would allow for release of risk adjustment data prior to reconciliation broadly, CMS understands that it is not always necessary and appropriate for risk adjustment data to be released prior to reconciliation. For example, relying on diagnosis information for research or program operations may not be appropriate before the final risk adjustment data submission deadline since plans have at least 13 months after the end of the service year to submit additional diagnoses for payment. CMS would review requests for the release of risk adjustment data prior to reconciliation to assess whether pre-reconciled data is necessary and appropriate for the requester's purpose. CMS's proposal to remove restrictions on the use and release of pre-reconciled risk adjustment data would provide greater flexibility in the release of risk adjustment data, supporting the goals of Executive Order 14243 "Stopping Waste, Fraud, and Abuse by Eliminating Information Silos" (March 20, 2025).

Additionally, by no longer restricting release to prescribed purposes, CMS is supporting the goals of Executive Order 14192 "Unleashing Prosperity through Deregulation" (January 31, 2025) by reducing the burden for CMS and external entities associated with the increasingly complex regulation that necessitates rulemaking when an unanticipated use of the data is identified.

CMS is seeking public comments on all aspects of the proposed revisions to the use and release of risk adjustment data at § 422.310(f) and allowing for greater flexibility in the release of data prior to the final risk adjustment data submission deadline.

D. Strengthened Documentation Standards for Part D Plan Sponsors

1. Background of Part D Coverage Determinations and Point-of-Sale (POS) Claim Adjudications

CMS regulations at § 423.566 specify that each Part D plan sponsor must have a procedure for making timely coverage determinations regarding the prescription drug benefits an enrollee is entitled to receive under the plan and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. In addition to a standard procedure for making such determinations, it must also have an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570. When a Part D plan sponsor requires a drug to be reviewed for coverage under Part D, there is coordination between the Part D plan sponsor and another entity, such as the prescriber, pharmacy, enrollee, or enrollee representative, to ensure that the drug meets the criteria for coverage prior to accepting the claim for payment under the Part D benefit.

Coverage determinations can be requested by the Part D enrollee, the enrollee's representative, or the prescriber on behalf of the enrollee. Current regulations at § 423.566(b) outline the actions that are considered Part D coverage determinations, such as a decision not to provide or pay for a Part D drug, including a decision not to pay because the drug is not on the plan's formulary, the drug is determined not to be medically necessary, the drug is furnished by an out-of-network pharmacy, or the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D.

A POS claim adjudication occurs when a claim is submitted by a pharmacy for payment after the presentation of a valid prescription, regardless of whether the Part D plan sponsor treats the POS transaction as a coverage determination. In general, Part D plan sponsors do not treat POS claim adjudications as coverage determinations.⁵⁰ However, Part D plan sponsors may implement utilization management edits in various situations to determine a drug's coverage at the POS. In such cases, the Part D sponsor may or may not choose to treat the POS claim adjudication as a coverage determination, leading to variance among plan sponsors. One reason a Part D plan sponsor might require a coverage determination or POS claim adjudication edit is to verify a drug's coverage under the Part D benefit. For example, Part D plan sponsors can use prior authorization for drugs with the highest likelihood of non-Part D covered uses, such as when coverage is available under Part A or Part B (versus D) for the drug as prescribed and dispensed or administered, or when the drug is not used for a medically accepted indication (MAI).⁵¹

Depending on the drug, Part D plan sponsors vary the scope of review when determining coverage or conducting a POS claim adjudication that determines coverage, and therefore, CMS must be able to review the plan sponsors' original documentation to ensure that a Part D plan sponsor asked relevant questions and received appropriate responses for the drug being reviewed. For example, in the instance of reviewing a drug for an MAI, the Part D plan sponsor needs to verify the diagnosis that led to the drug being prescribed to ensure that it is being prescribed and dispensed for an MAI and is eligible for coverage under Part D.

2. Audits of Part D Program Integrity Prescription Drug Event Records

Under section 1860D–12(b)(3)(C) of the Act and 42 CFR 423.505(d)–(e), Part D plan sponsors are required to maintain certain categories of documentation for specified periods of

⁵⁰ Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Section 40.2 (found at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf>).

⁵¹ Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, Section 30.2.2.3 (found at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>).

time. Specifically, § 423.505(d) requires that the contract between a Part D plan sponsor and CMS include an agreement by the Part D plan sponsor to maintain books, records, documents, and other evidence of accounting procedures and practices for 10 years that are sufficient to meet certain requirements, including enabling CMS to evaluate the quality, appropriateness, and timeliness of services performed under the contract and to audit the services performed or determinations of amounts payable under the contract. In addition, § 423.505(e) requires that Part D plan sponsors agree to allow HHS, the Comptroller General or their designee to evaluate through audit, inspection, or other means (1) the quality, appropriateness, and timeliness of those services furnished to Medicare enrollees; (2) compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees; (3) facilities of the Part D sponsor; and (4) enrollment/disenrollment records for the current contract period and 10 prior periods. Furthermore, §§ 423.568(a)(3), 423.570(c)(2), and 423.584(c)(1) outline requirements for Part D plan sponsors to establish and maintain a method of documenting and to retain documentation for oral requests for coverage determinations under standard timeframes, expedited timeframes, and redeterminations respectively.

Although the statute and current regulatory requirements address documentation maintenance and availability, these requirements do not detail the documentation needed to be maintained to support the appropriateness of a Part D coverage determination or POS claim adjudication that is used to determine coverage under the Part D benefit. The availability of complete and accurate documentation in its original format (for example, fax, call notes, electronic PA), is a key component of ensuring that taxpayer dollars are spent appropriately in the Part D program. Through CMS's Part D program integrity prescription drug event (PDE) record review audits, we have observed a large degree of variation among the documentation that Part D plan sponsors maintain when conducting coverage determinations, including prior authorizations, and POS claim adjudication edits, used to determine a drug's coverage under Part D, and subsequently provide to CMS upon audit. While some Part D plan sponsors have robust documentation standards that outline the information

the Part D plan sponsor obtained that led to coverage under the Part D benefit, others provide or maintain little to no documentation. In some instances, plan sponsors maintain a summary of the original coverage request or refer to a past coverage determination to extend an authorization. In these instances, CMS is unable, upon audit, to review the original documentation to ensure that the information obtained was accurate. For CMS to provide proper oversight of the Part D program and the approvals made for drugs covered under the Part D benefit, it is imperative that Part D plan sponsors provide and maintain original documentation that describes how and why the Part D plan sponsor approved a drug for coverage. Without sufficient documentation, CMS cannot fully review, during an audit or educational analyses, or other program integrity efforts, Part D plan sponsor coverage determinations and POS claim adjudications for accuracy. The standardization and availability of sufficient documentation to support a drug's coverage under the Part D benefit will allow CMS to conduct more effective audits and help ensure CMS can verify that a drug was accurately paid under Part D.

3. Proposed Provisions

We are proposing standardized, detailed documentation requirements for coverage determinations and POS claim adjudications, used for purposes of determining coverage under the Part D benefit. We are proposing documentation requirements that include but are not limited to certain written, verbal, and electronic communications, such as the date and time the request was received; the name and title of the individual who submitted or verified the request; and the information used to make the coverage determination. These requirements would not apply to POS claim adjudications for purposes that are unrelated to the determination of coverage under the Part D benefit or the correct Medicare benefit for coverage, such as those POS claim adjudications for safety, dose limitations, and quantity limits. Any additional documentation recorded or maintained will be subject to existing protected health information (PHI) and personally identifiable information (PII) rules and regulations.

Specifically, we propose the following revisions to the documentation requirements:

- First, to revise § 423.505(d)(1) to add new paragraph (vi) to enable CMS to review original format documentation or information from all written, electronic, and verbal communications

between the pharmacist, prescriber, enrollee, or other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon by the Part D plan sponsor to make a coverage determination or otherwise permit a point-of-sale claim adjudication that determines a drug's coverage under the Part D benefit. In instances when a coverage determination is extended, the original coverage determination must be maintained as documentation. The documentation covered by these standards must be made available to CMS during Part D program integrity prescription drug event (PDE) record review audits. Failure to produce this documentation will result in an improper Part D audit determination and will be subject to PDE record deletion in accordance with § 423.325(a)(2).

- Second, to revise § 423.505 to add the following new paragraphs:

- ++ Paragraph (d)(2)(xiii) to include all documentation or information from all written, electronic, and verbal communications between the pharmacist, prescriber, enrollee, or other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon when a Part D plan sponsor makes a coverage determination or otherwise permit a point-of-sale claim adjudication that determines coverage of a drug under the Part D benefit, consistent with paragraph (d)(1)(vi). This includes:

- ++ Paragraph (d)(2)(xiii)(A) to include the date and time the request for a coverage determination or point-of-sale claim adjudication was received and the identity of the individual who submitted the request.

- ++ Paragraph (d)(2)(xiii)(B) to include the name and title (as applicable) of the individual the Part D plan sponsor contacted to verify the request (for example, pharmacist, prescriber, enrollee, or enrollee representative).

- ++ Paragraph (d)(2)(xiii)(C) to include information obtained, including the questions asked and the responses received, and the final decision rendered.

- ++ Paragraph (d)(2)(xiii)(D) to include the diagnosis code for a coverage determination or point-of-sale claim adjudication used to support a medically accepted indication.

- ++ Paragraph (d)(2)(xiii)(E) to include any additional information that the Part D plan sponsor utilized to determine the final outcome of the coverage determination or point-of-sale claim adjudication request.

- Third, to revise § 423.505(e)(2) to add a phrase to reference the

requirement to make available the records containing information used to make the coverage determination or POS claim adjudication.

E. Updating Third-Party Marketing Organizations (TPMO) Disclaimer Requirements (§§ 422.2267 and 423.2267)

As a part of the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Final Rule which appeared in the **Federal Register** on May 9, 2022 (hereafter referred to as the May 2022 final rule) (87 FR 27704), as a part of a broader effort to address concerns with TPMOs, CMS finalized regulations at §§ 422.2267(e)(41) and 423.2267(e)(41) to improve regulatory oversight of Third-Party Marketing Organizations (TPMOs). One provision required Medicare Advantage (MA) organizations and Part D sponsors to ensure that the TPMOs, with whom MA organizations and Part D sponsors directly or indirectly do business, verbally convey a standardized disclaimer during sales calls with beneficiaries. CMS implemented these regulations after listening to TPMO-based sales calls and hearing first-hand beneficiary confusion about the information the TPMO was conveying and to help ensure that TPMOs were not marketing information in a misleading way that might lead beneficiaries to join a plan contrary to their intention, or a plan that did not best meet their health care needs. The disclaimer, as finalized, consisted of the following statement: “We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact *Medicare.gov* or 1-800-MEDICARE to get information on all of your options.”

After these regulations were implemented, CMS continued to monitor TPMOs’ interactions with beneficiaries during these sales calls. In CMS’s review of hundreds of sales, marketing, and enrollment audio calls, CMS found that only one plan option from one MA organization was discussed in over 80 percent of the calls reviewed. These reviews also showed that TPMOs rarely, if ever, informed the beneficiary that there were multiple plans available in their service area. Although the TPMO may have researched other plans, the TPMO rarely communicated information about those

plan options to the beneficiary; thus, the beneficiary may not have known about other available options. These monitoring efforts heightened CMS’s concern that beneficiaries were not receiving comprehensive information about all their plan choices, thus limiting their ability to make an informed decision about the plan best able to meet their health care needs.

To address those concerns, CMS issued the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program; and Programs of All-Inclusive Care for the Elderly Final Rule, hereinafter referred to as the April 2023 final rule (88 FR 22120). In this final rule, CMS amended §§ 422.2267(e)(41) and 423.2267(e)(41) revising the existing disclaimer, which was applicable to TPMOs that represented more than one, but not all, MA organizations or Part D sponsors in a given service area, to notify the beneficiary about the number of organizations and the number of plans the organizations offered. Additionally, CMS revised §§ 422.2267(e)(41) and 423.2267(e)(41) to include a new required disclaimer for TPMOs that contracted with every MA organization or Part D sponsor in a service area. Finally, CMS added State Health Insurance Assistance Programs (SHIPs) as a source of information for beneficiaries to both versions of the disclaimer and required TPMOs convey the applicable disclaimer within the first minute of a sales call, among other requirements for the TPMP to communicate the disclaimer through other electronic means or materials (as described under §§ 422.2267(e)(41) and 423.2267(e)(41)).

In the April 2023 final rule, CMS addressed comments received in response to the proposed rule (88 FR 22120). Some industry stakeholders raised concerns about the new disclaimer requirements. For example, some asserted that requiring TPMOs to list all the plans with which they contract would confuse or distract beneficiaries; or for those TPMOs that represent many plans, the disclaimer would be too long to read within the first minute. Similarly, some stakeholders pointed out that budget constraints and limited training would hinder a SHIP’s ability to effectively assist beneficiaries with plan choices. While CMS understood those concerns, given CMS’s observations about common TPMP interactions with beneficiaries during the sales and enrollment calls previously described,

the agency determined that these regulatory changes were warranted.

CMS regularly reviews MA and Part D program requirements and how they affect Medicare beneficiaries and industry stakeholders. Based on CMS’s review and industry feedback, CMS determined that additional changes to the TPMP disclaimer may be appropriate. CMS is proposing to modify the TPMP disclaimer requirement in §§ 422.2267(e)(41) and 423.2267(e)(41) to: (1) replace the existing requirement to read the disclaimer within the first minute of the call, so that TPMOs are instead required to read the disclaimer “prior to the discussion of any benefits” during the call, and to: (2) remove SHIPs as a source of information from the disclaimer. CMS has determined that requiring TPMOs to convey the disclaimer during the first minute of a sales call is not always the appropriate time to notify the beneficiary of the number of plan choices available. CMS believes that many calls typically begin with the TPMP obtaining basic demographic information from the beneficiary, which allows the TPMP to immediately determine if the call should proceed to the benefit discussion phase. In other instances, the TPMP may determine that the beneficiary does not have a valid election period, which would end the call, making the disclaimer unnecessary. Notifying the beneficiary of the number of plans that a TPMP represents in the first minute does not always promote clear communication with the beneficiary or mitigate beneficiary confusion. By permitting TPMOs to read the disclaimer at an appropriate point during the call, provided it is read prior to the discussion of any benefits, the disclaimer will fit in better with the flow of the conversation. CMS does not consider the mere mention of a benefit, for example pointing out that nearly all MA organizations offer routine dental care, constitutes a discussion of benefits. Rather, CMS believes that discussing the specificity of a benefit with the intent to draw a beneficiary’s attention to an MA or Part D plan(s), or to influence a beneficiary’s decision-making process when making an MA or Part D plan selection, or to influence a beneficiary’s decision to stay enrolled in a plan, could represent a discussion of benefits, as defined by the marketing definition under §§ 422.2260 and 423.2260. This could include, for example, talking with a beneficiary about the benefits listed in a plan’s Evidence of Coverage document, or how beneficiary out of pocket cost sharing

might work given a plan's benefit structure and the beneficiary's previous health care experience or needs. If there is no discussion of benefits, CMS would not expect TPMOs to provide the disclaimer to beneficiaries. CMS seeks comment on how the Agency should identify when a "discussion of benefits" occurs.

CMS is proposing changes only to the TPMO disclaimer provision at §§ 422.2267(e)(41)(ii) and 423.2267(e)(41)(ii). Thus, this proposal would not alter the existing requirements provided within §§ 422.2267(e)(41)(i), (iii), (iv), and (v); and 423.2267(e)(41)(i), (iii), (iv), and (v). That is, any TPMO, as defined under §§ 422.2260 and 423.2260, that sells plans on behalf of more than one MA organization or Part D sponsor, must electronically convey the TPMO disclaimer when communicating with a beneficiary through email, online chat, or other electronic means of communication, prominently display the disclaimer on TPMO websites, and include the disclaimer in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

CMS is also proposing to remove SHIPs as a source of information from the disclaimer. CMS recognizes that, while SHIPs can be a source of unbiased information about plan choices, informing beneficiaries on every sales call about the SHIP may cause additional issues. SHIP volunteers may not always have the expertise to help beneficiaries navigate increasingly complex MA and Part D programs. CMS believes that beneficiaries enrolled in the MA and Part D programs may be more effectively served by information and entities for which CMS has direct oversight. Moreover, a recent article in the Journal of the American Medical Association Network⁵² details a study conducted to determine if SHIP counselors provided accurate and complete information to Medicare beneficiaries about their coverage options. In this study, mystery shoppers posed as individuals newly eligible for Medicare. While over 94 percent of the responses differentiating Original Medicare from MA were accurate, fewer than half of counselors mentioned Dual-Eligible Special Needs Plans (D-SNPs) as an option for mystery shoppers posing as dually eligible beneficiaries. The results suggested that SHIPs may not always be able to address the needs of Medicare beneficiaries seeking

unbiased information on coverage options

CMS also recognizes that each SHIP works differently and provides different training to its counselors, which can vary further at the local level. This can result in Medicare beneficiaries receiving different information based on the SHIP and SHIP counselor that is ultimately reached. CMS believes that, for the TPMO disclaimer, 1-800-MEDICARE is a better option to assist beneficiaries with health care choices. 1-800-MEDICARE has representatives available 24/7 to assist beneficiaries, provides standardized training to its customer service representatives, is centrally monitored and controlled by CMS, which facilitates efficient and consistent information sharing, and is a one-stop shop for all beneficiaries, regardless of the state in which they live.

For reasons previously discussed, CMS is proposing to revise §§ 422.2267(e)(41) and 423.2267(e)(41) to remove references to the SHIPs, while maintaining guidance for beneficiaries to contact *Medicare.gov* or 1-800-MEDICARE for plan advice. Additionally, CMS is proposing to revise §§ 422.2267(e)(41)(ii) and 423.2267(e)(41)(ii) to require TPMOs to provide the TPMO disclaimer during sales calls before engaging in discussions about benefits rather than requiring TPMOs to verbally convey the disclaimer during the first minute of a sales call.

CMS solicits comment on this proposal.

F. Removing Rules on Time and Manner of Beneficiary Outreach (§§ 422.2264, 423.2264, 422.2274, and 423.2274)

Section 1851(h) and (j) of the Act provides a structural framework for how MA organizations may market and communicate with beneficiaries and directs CMS to adopt standards related to prohibitions and limitations on marketing and communications activities. Section 1860D-1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) of the Act relating to approval of marketing material and application forms for Part D sponsors. Section 1860D-4(l) of the Act applies certain prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations (and agents, brokers, and other third parties representing MA organizations).

CMS has adopted regulations related to marketing and communications by MA organizations and Part D sponsors in 42 CFR part 422, subpart V, and 42

CFR part 423, subpart V; these regulations include the specific standards and prohibitions in the statute as well as standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under 42 CFR 417.428, most marketing and communications requirements in subpart V of part 422 also apply to section 1876 cost plans. CMS has long provided further interpretation and sub-regulatory guidance for these regulations in the form of a manual titled, "Medicare Communications and Marketing Guidelines" (MCMG), previously known as "Medicare Marketing Guidelines." Because this proposed rule is applicable to MA organizations, Part D sponsors, and cost plans, CMS refers to each of these regulated entities as a "plan."

In the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule (hereinafter referred to as the January 2021 final rule), CMS codified guidance contained in the MCMG by integrating it with existing regulations. In the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule (hereinafter referred to as the April 2023 final rule), CMS then finalized several changes to 42 CFR parts 422 and 423, subpart V, to strengthen beneficiary protections and improve MA and Part D marketing.

In this current proposed rule, CMS is proposing several changes to requirements regarding the time and manner of plans' outreach to beneficiaries. The primary proposals include three changes to §§ 422.2264(c) and 423.2264(c) to remove rules on the time and manner of beneficiary outreach. In addition, at §§ 422.2264(c)(3), 423.2264(c)(3), 422.2274(b)(3), 423.2274(b)(3), 422.2274(c)(9)(ii), and 423.2274(c)(9)(ii), CMS is proposing a few other regulatory changes to add specificity and clarify policy. In total, these proposals and clarifications are designed to improve the enrollment decision-making process by creating a more convenient, beneficiary-friendly outreach experience and to reduce the burden on beneficiaries, plans, and agents/brokers. Furthermore, these proposals align with the January 31, 2025, Executive Order 14192, "Unleashing Prosperity Through

⁵² https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2832052#google_vignette.

Deregulation” (hereinafter referred to as E.O. 14192).⁵³ E.O. 14192 describes the Administration’s policy goals to promote prudent financial management and alleviate unnecessary regulatory burdens. Section 2 of E.O. 14192 states that it is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people. The changes CMS proposes here are deregulatory and therefore support the Administration’s policy goals.

1. Marketing Events Following Educational Events in Same Location

In the January 2021 final rule, CMS codified guidance existing in the MCMG regarding events with beneficiaries. The finalized regulation text at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) required that if a marketing event directly followed an educational event, the beneficiary must be made aware of the change from an educational to a marketing event and be given the opportunity to leave prior to the marketing event beginning. In the April 2023 final rule, CMS modified §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) to prohibit marketing events from taking place within 12 hours of an educational event in the same location (that is, the entire building or adjacent buildings). This prohibition was intended to protect beneficiaries from feeling pressured to stay for a marketing event after having attended an educational event. However, it also created additional barriers for plans or agents/brokers as well as beneficiaries who wished to discuss potential enrollment options with respect to specific plan products following an educational event.

As described in the April 2023 final rule, approximately half of the commenters opposed this provision. Some commenters stated that agents/brokers were not hurting seniors by holding a marketing event after an educational event, that this provision would result in beneficiaries being upset with agents/brokers for something that is out of their control, that it would not add any additional protection from marketing abuses, that it would degrade the consumer experience, and that the proposal was both heavy-handed and unworkable. Furthermore, some commenters were concerned that the number of educational events would decrease, resulting in beneficiaries being less informed regarding plan options

overall and increasing the likelihood of a beneficiary enrolling in a plan that did not meet their health care needs. Other commenters said that the 12-hour delay was burdensome, specifically for dually eligible, low-income, disabled, and other underserved beneficiaries, who might experience transportation barriers or lack access to transportation. Such barriers factor in when beneficiaries are forced to travel to separate locations to attend an educational event and a separate marketing event 12 or more hours later, thus making access to information and resources in just one interaction a critical component. For greater detail on the different types of burden potential identified by commenters, see the April 2023 final rule.

Following the April 2023 final rule, CMS has continued to receive stakeholder feedback reiterating concerns about the burden placed on both plans or agents/brokers and beneficiaries regarding the 12-hour delay requirement. While CMS considered similar hypothetical concerns prior to finalizing the April 2023 rule, the agency is now reconsidering these requirements based on valuable input, such as the real-world experience cited in stakeholder feedback. After reevaluating these impacts, CMS is concerned that the requirements at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) do impose an unnecessary burden on beneficiaries and plans and agents/brokers. Furthermore, CMS believes, based on stakeholder input, that the 12-hour delay requirement between an educational event and a marketing event may also create an unnecessary barrier to accessing important MA and Part D information for beneficiaries, especially those who live far from the events or those who lack access to transportation. Moreover, based on a lack of evidence of a quantifiable protection to the beneficiary from the existing regulatory requirement, CMS believes that the beneficiary protections that CMS previously identified in the April 2023 final rule have not materialized. For example, in the April 2023 final rule, CMS explained that its concern about inappropriate pressure on beneficiaries (especially dually eligible individuals and other vulnerable groups) that may occur when marketing events occur directly after educational events outweighed some of the access and transportation concerns. However, CMS is now reconsidering these previous positions taken in 2023 because for vulnerable beneficiaries, especially those in SNPs, it is common to have

caregivers or other friends or family members provide assistance in gathering information on plan options (and often ultimately make decisions on behalf of the beneficiary), thus, there is often a built-in layer of added protection from any potential undue pressure. CMS notes that there are also various beneficiary protections in place, including the possibility of providing special enrollment periods (SEPs) when appropriate, or, if warranted, processing a retrospective enrollment to place the beneficiary back into their prior coverage, if a beneficiary makes an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics. CMS thus proposes that plans and agents/brokers should be able hold an educational event and a marketing event back-to-back and in the same location.

For these reasons, CMS is proposing to eliminate the 12-hour delay requirement, so that a marketing event may take place directly following and in the same location as an educational event. This proposal aligns with section 1851(j)(1)(D)(ii) of the Act, which prohibits sales and marketing activities at educational events but does not require a specific timeframe between an educational event and a marketing event. This proposal, permitting marketing events to follow educational events, provided there is an appropriate break, is consistent with the statutory requirement. CMS is proposing to amend paragraph (c)(2)(i) in both §§ 422.2264 and 423.2264 to state that if a marketing event directly follows an educational event, plans and agents/brokers would be required to notify the beneficiary that the educational event is ending and a marketing event will begin shortly. Examples of appropriate beneficiary notification might be in the form of a verbal announcement at the educational event or a clear and distinct notation on a written schedule of the day’s event. In addition to the beneficiary notification, CMS is proposing that plans and agents/brokers would also be required to give the beneficiary a sufficient opportunity to leave the educational event prior to the start of the marketing event. An example of “a sufficient opportunity to leave” appropriately given by the plan or agent/broker would be a brief restroom or snack break between the educational event and the marketing event. This deregulatory change is expected to significantly reduce burden and cost for plans and agents/brokers in terms of event planning. It would also likely ease burden on beneficiaries when they attend an educational event and

⁵³ <https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/>.

subsequently want to obtain more plan-specific information at a marketing event. By allowing both types of events to occur at the same location once beneficiaries are made aware of both events and given a sufficient opportunity to leave, beneficiaries would not need to return on a different day or to a different venue to attend a marketing event. As such, this proposal would provide greater convenience for beneficiaries and enhance the beneficiary experience in shopping for a plan.

2. Timing of Personal Marketing Appointment After Scope of Appointment (SOA) Form Completion

Sections 1851(j)(2)(A) and 1860D–4(l)(2) of the Act direct that the Secretary shall establish limitations with respect to the scope of any marketing appointment and that such limitation shall require advance agreement with a prospective enrollee on the scope of the marketing appointment and that documentation of such agreement must be done by the plan. In situations where the marketing appointment is in person, the statute further provides that such documentation shall be in writing. The advance agreement documentation is commonly referred to as the Scope of Appointment (SOA) form. The SOA requirement helps to ensure beneficiaries understand what types of plans will be discussed prior to meeting with a plan or an agent/broker.

Over the course of the past several years, CMS SOA policy has evolved as reflected in CMS's regulatory requirements. This is in part due to changes in the MA market over time, which has led to an evolving understanding of what measures may be appropriate to regulate for improper marketing activities and to ensure that beneficiaries are able to make informed decisions about their enrollment choices. CMS first codified the SOA statutory requirement at §§ 422.2268(g) and 423.2268(g) in the Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs Interim Final Rule with Comment Period (hereinafter referred to as the September 2008 IFC) (73 FR 54226), prohibiting plans from marketing during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment occurring. Aligning with the statute, CMS explained that the beneficiary must have the opportunity to agree to the range of choices that will be discussed, and that agreement would have to be documented. Then in the

Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs Final Rule (hereinafter referred to as the September 2011 final rule) (76 FR 54634), CMS modified §§ 422.2268(g) and 423.2268(g) by designating a specific timeframe standard for the SOA advance agreement—48 hours in advance of the marketing appointment, when practicable. This CMS interpretation was also memorialized in the MCMG at the time. In the January 2021 final rule, CMS made some structural changes to 42 CFR part 422, subpart V, and 42 CFR part 423, subpart V, removed §§ 422.2268 and 423.2268, and shifted the SOA rule to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i). Also, in this January 2021 final rule (86 FR 5890), CMS removed the 48-hour SOA standard again, stating that prior to the personal marketing appointment beginning, the plan (or agent/broker, as applicable) must agree upon and record the SOA with the beneficiary(ies).

In the April 2023 final rule, CMS reverted to the 48-hour SOA standard, prohibiting personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary. However, this change did not include the previously codified “when practicable” because CMS, at the time, believed this phrase nullified the purpose of the 48-hour timeframe given the various reasons why waiting 48 hours may not be practicable.⁵⁴ Therefore, in the April 2023 final rule (88 FR 22336), CMS added the phrase “At least 48 hours” to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to require such a timeframe prior to the personal marketing appointment for the SOA to be agreed upon and recorded with the beneficiary. CMS also finalized two exceptions to the 48-hour SOA rule—one for SOAs that are completed during the last four days of a valid election period for the beneficiary and the other for unscheduled in-person meetings (walk-ins) initiated by the beneficiary (see §§ 422.2264(c)(3)(i)(A)–(B) and 423.2264(c)(3)(i)(A)–(B)). These are the current policies for the 48-hour SOA rule.

Similar to the reasoning for proposing to eliminating the 12-hour delay

requirement at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i), CMS believes that the strict 48-hour SOA requirement may create an unnecessary barrier to accessing important MA and Part D information for impacted beneficiaries, and also barriers for plans and agents/brokers distributing this information, without offering a quantifiable protection to the beneficiary. For example, after both the September 2011 final rule and the April 2023 final rule, CMS received numerous inquiries from plans and agents/brokers questioning the logistics of the 48-hour SOA rule and objecting to the rule's tendency to create obstacles to promoting beneficiaries' smooth, informed, and timely decision-making when faced with various enrollment options. The 48-hour delay may have a negative impact on a beneficiary's freedom to engage with a plan or an agent/broker on a schedule that works best for them. On the other hand, the 48-hour delay may require a beneficiary to dedicate more time than they wished to spend should they wish to engage with multiple plans or agents/brokers and need to wait 48 hours before engaging with them and deciding in which plan they wish to enroll.

Consequently, CMS is proposing to eliminate the 48-hour waiting period required between the SOA completion and a personal marketing appointment, as well as eliminate the two corresponding exceptions to the 48-hour SOA rule. Under this proposal, plans and agents/brokers would no longer be required to wait 48 hours between obtaining an SOA and speaking with a beneficiary about plan products. Beneficiaries would be able to learn about plan products in real time, rather than having to come back for a personal marketing appointment 48 hours later. This rule, if finalized, would still require an advance agreement, as statutorily required, but without a specified timeframe. Beneficiaries would be able to fill out an SOA just prior to discussing plan products or may fill out an SOA for a future personal marketing appointment. For this proposed change, paragraph (c)(3)(i) in both §§ 422.2264 and 423.2264 would revert to its original language as finalized in the January 2021 final rule by removing the phrase “At least 48 hours” and the phrase “, except for:” and by removing the two exceptions listed at paragraphs (c)(3)(i)(A) and (B). CMS is also proposing a minor technical correction in § 422.2264(c)(3)(i) to add the missing word “appointment” after “marketing.”

CMS believes that eliminating the 48-hour SOA rule would benefit all parties,

⁵⁴ For more details, please refer to the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications Proposed Rule (hereinafter referred to as the December 2022 proposed rule).

especially beneficiaries, by allowing for a discussion of plan products on the beneficiary's schedule. Similar to the 12-hour delay requirement between an educational event and a marketing event, the 48-hour SOA rule potentially inhibits a beneficiary from receiving information. While the current requirement has an exception for in-person meetings (walk-ins) initiated by the beneficiary, it does not account for other interactions that may take place between the beneficiary and a plan or an agent/broker. For example, beneficiaries who live far away or those with transportation issues who sign an SOA with a plan or an agent/broker when attending a marketing event would be required to come back no less than 48 hours later to meet with that plan or agent/broker again.

CMS acknowledges that in the April 2023 final rule, CMS stated that the burden caused by the 48-hour SOA rule was outweighed by the potential benefit of providing beneficiaries, especially vulnerable beneficiaries, time to speak with caregivers and others who they may rely upon for help or advice or just provide the beneficiary additional time to consider their options. However, CMS believes that a different approach may be appropriate now for a similar reason as mentioned for the proposal to eliminate the 12-hour delay requirement. There is often a built-in layer of added protection from any potential undue pressure, as evidenced by the tendency for vulnerable beneficiaries to have other people help them with plan options and making decisions (for example, caregivers or authorized representatives), together with previously mentioned existing beneficiary protections if a beneficiary makes an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics. CMS is now reexamining the relative protection offered by these other factors and based on additional information that CMS has received about the relative benefit or burden of the 48-hour SOA rule. As described earlier in the proposal, since the September 2011 final rule, and more recently, the April 2023 final rule, CMS has received numerous clarifying questions regarding the 48-hour timeframe, as well as stakeholder commentaries providing anecdotal and hypothetical concerns and reasons why the 48-hour SOA rule may be harmful to beneficiaries. Criticism regarding the potentially adverse effects on beneficiaries led CMS to further review the unintended consequences of the "cooling off" period. This leads CMS to conclude that it may be appropriate for

plans and agents/brokers to meet with the beneficiary or the beneficiary's representative sooner than 48 hours after the collection of the SOA form. In other cases, the plan or agent/broker may need to travel long distances, possibly hundreds of miles, to have a follow-up appointment based on the current 48-hour SOA rule, therefore, the proposal here would also reduce the burden on plans and agents/brokers in addition to beneficiaries and their representatives.

Furthermore, by returning to the same regulatory language as in the January 2021 final rule (and similar language as in the September 2008 IFC)—which aligned with section 1851(j)(2)(A) of the Act—CMS is closely aligning with statute. CMS believes this proposal to eliminate the 48-hour SOA rule is consistent with the statutory requirement at section 1851(j)(2)(A) of the Act that requires an advance agreement with a prospective enrollee, given the statute does not define the timeframe between the agreement and the marketing appointment with the plan or agent/broker.

In conjunction with proposing to eliminate the 48-hour SOA rule, CMS is also proposing a few additional associated regulation changes and clarifying various SOA policies that would further bolster the precision of the remaining requirements should the agency finalize the elimination of the 48-hour SOA rule. CMS has received questions from plans and agents/brokers regarding SOA policies, and these proposed regulation changes and policy clarifications are necessary and responsive to those questions. CMS is requesting that plans and agents/brokers review the following information carefully and provide feedback through the comment process. If this portion of the rule is finalized as proposed, the SOA policy clarifications contained herein will supersede any existing SOA guidance.

First, CMS is proposing to more clearly define what qualifies as a personal marketing appointment. The introductory language at §§ 422.2264(c)(3) and 423.2264(c)(3) currently states that personal marketing appointments are those appointments that are tailored to an individual or small group and that personal marketing appointments are not defined by the location. CMS proposes to clarify this regulatory definition by adding language to paragraph (c)(3) in both §§ 422.2264 and 423.2264 stating that personal marketing appointments are for purposes of discussing marketing topics, so that the proposed language reads as follows: "Personal marketing

appointments are those appointments that are tailored to an individual or small group (for example, a married couple) for purposes of discussing marketing topics."

In addition to this proposed change to the regulatory text, CMS is also clarifying here that a small group, for purposes of an SOA, is a limited number of people, generally related or living in the same household. While the regulation provides an example of a married couple, another example would be a parent and child who are both Medicare-eligible. Meetings with unrelated beneficiaries in a home or a public space, such as a book club at a house or a small group at a library, would require separate SOAs for each individual. In addition, §§ 422.2264(c)(3) and 423.2264(c)(3) state that personal marketing appointments are not defined by the location, meaning that such an appointment could take place in-person, telephonically, or virtually.

For more context on what a personal marketing appointment is, CMS reminds plans and agents/brokers of the types of activities that may take place at such an appointment. Per §§ 422.2264(c)(3)(ii) and 423.2264(c)(3)(ii), plans and agents/brokers holding a personal marketing appointment may do any of the following: (1) provide marketing materials; (2) distribute and accept plan applications; (3) conduct marketing presentations; and (4) review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

Following the introductory definition of a personal marketing appointment, §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) describe the current 48-hour SOA rule. CMS is proposing to remove the word "scheduled" before "personal marketing appointment" at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i), so that the proposed text would state that "prior to the personal marketing appointment," the MA/Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies). Likewise, CMS is proposing to amend §§ 422.2274(b)(3) and 423.2274(b)(3) to more closely align with §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) by replacing "prior to meeting with potential enrollees" with "prior to a personal marketing appointment." CMS believes these regulatory text changes are necessary to avoid ambiguity and prevent misinterpretation.

If finalized as proposed, CMS's removal of the word "scheduled" would mean that an SOA would be required for

all appointments that meet the definition of personal marketing appointments. For example, an SOA would be required for plan/agent/broker-initiated outbound contact and for beneficiary-initiated inbound contact (including walk-ins, unscheduled calls and web-based chats, and web-based forms), as long as the contact is tailored to an individual or small group (as explained earlier in the proposal) for purposes of discussing marketing topics. To be clear, this means that an SOA would be required regardless of whether the personal marketing appointment was initiated by the plan, an agent/broker, or the beneficiary.

Other relevant requirements regarding the SOA are related to the method of delivery and where SOAs may and may not be accepted or collected. In order to align with the statutory requirements at section 1851(j)(2)(A) of the Act, CMS is proposing to add that the SOA must be in writing for in-person personal marketing appointments by adding new regulatory text to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i). This proposed change mirrors the statutory requirement which provides that if the marketing appointment is in person, then the SOA must be in writing. The proposed new regulatory text at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) would read, “The Scope of Appointment must be in writing for in-person personal marketing appointments.” Additionally, §§ 422.2274(c)(9)(ii) and 423.2274(c)(9)(ii) require agents/brokers to establish and maintain a system for confirming that agents/brokers appropriately complete SOA records for all marketing appointments (including telephonic and walk-in). Here, CMS is proposing to add the word “personal” to §§ 422.2274(c)(9)(ii) and 423.2274(c)(9)(ii), so that it reads “personal marketing appointments” to ensure consistency with the other regulation sections previously mentioned. CMS is also clarifying that there are many ways that an agent/broker can complete an SOA record. For example, an audio or audio-visual recording or an electronic record would suffice as an SOA record for a personal marketing appointment that does not occur in person. Instances in which SOAs may be accepted or collected include: (1) plan activities in the health care setting (§§ 422.2266(e)(1) and 423.2266(e)(1)); (2) marketing events (§§ 422.2264(c)(2)(ii)(C) and 423.2264(c)(2)(ii)(C)); and (3) educational events—if the proposed changes to §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D) are finalized as

proposed. Instances in which SOAs may not be accepted or collected include: (1) plan-initiated provider activities (§§ 422.2266(d)(1)(i) and 423.2266(d)(1)(i)); and (2) activities performed by social workers of an I-SNP (employees, agents, or contracted providers) (§ 422.2266(f)(3)).

Regarding the content of the SOA, CMS is clarifying here that, because §§ 422.2264(c)(3)(iii) and 423.2264(c)(3)(iii) require that plans and agents/brokers holding personal marketing appointments may not market any health care related product during an appointment beyond the scope agreed upon by the beneficiary and documented in an SOA, the SOA must therefore include, at a minimum, the type of product(s) to be discussed. This aligns with section 1851(j)(2)(A) of the Act’s reference to “the scope of the marketing appointment.” Examples of types of products to be discussed include, but are not limited to, MA plans, MA-PD plans, and standalone PDPs. As a best practice, in addition to the type of product(s) to be discussed, CMS encourages plans to also include other pertinent information in the SOA, such as the date of the appointment and beneficiary contact information. In addition, on the SOA form, CMS permits plans to have check boxes or requests from the beneficiary regarding the type of product(s) to be discussed, for example, an internet site with an online form that requests a plan or an agent/broker to contact the beneficiary. Provided this type of SOA form addresses the type of product(s) to be discussed, the plan or agent/broker may contact the beneficiary after the form has been filled out. CMS also clarifies that Business Reply Cards (BRCs), voicemails, online forms, or other requests for information that include the type of product(s) to be discussed are, in effect, SOAs. CMS currently does not provide a model document for SOAs.

Lastly, CMS would like to remind plans and agents/brokers of and clarify the requirements regarding the validity time period for an SOA. Pursuant to §§ 422.2264(c)(3)(iii)(A) and (B) and 423.2264(c)(3)(iii)(A) and (B), SOAs, BRCs, and other requests for additional information are valid for 12 months following the beneficiary’s signature date or the date of the beneficiary’s initial request for information. During this 12-month period, plans or agents/brokers may contact beneficiaries regarding the agreed upon scope of products documented in the SOA. This does not grant permission to discuss products not previously agreed upon in the original SOA; any new product discussion outside the scope previously

agreed upon would require a new SOA. This includes the same product for a different year (for example, if there is an SOA to discuss contract year 2026 plans, then a new SOA would be required to discuss contract year 2027 plans). Finally, the signed SOA can be used for multiple telephonic or in-person contacts or appointments. With that said, a plan or agent/broker should respect a beneficiary’s request to no longer be contacted, even if that additional contact would take place within the 12-month window.

3. Scope of Appointment (SOA) Forms at Educational Events

In the January 2021 final rule, at §§ 422.2264(c)(1)(ii)(E) and 423.2264(c)(1)(ii)(E), CMS codified rules permitting plans and agents/brokers holding or participating in educational events with beneficiaries to obtain beneficiary contact information, including SOA forms, at educational events. In the April 2023 final rule, at §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D), CMS finalized rules that revised these regulations by prohibiting plans and agents/brokers from making available and receiving SOA forms from beneficiaries at educational events (other forms of beneficiary contact information, including BRCs, were still permitted). This is the current policy regarding SOA forms at educational events.

CMS is proposing to rescind these requirements as finalized in the April 2023 final rule and revert to the language established in the January 2021 final rule, to permit plans and agents/brokers to obtain SOA forms at educational events. Although section 1851(j)(1)(D)(ii) of the Act prohibits sales and marketing activities from occurring at educational events, the statute does not prohibit the collection of SOA forms at educational events. The collection of an SOA form is not a sales or marketing activity but is the making of an agreement regarding what type of product(s) will be discussed in advance of a personal marketing appointment between the beneficiary and the plan or agent/broker. By permitting plans and agents/brokers to obtain SOA forms at educational events, the burden on beneficiaries, plans, and agents/brokers would be reduced, and parties would be allowed to conveniently schedule personal marketing appointments to discuss plan options in the future, instead of having to wait until after the educational event ends to schedule an appointment. If plans and agents/brokers are allowed to collect SOAs at educational events, then it decreases the likelihood that beneficiaries might face

undue burden and the potential challenge of reconnecting with a plan or agent/broker or traveling back to a venue to locate a plan or agent/broker at the conclusion of an educational event.

CMS acknowledges that this proposal reflects a change in the agency's position as described in the April 2023 final rule where CMS most recently adopted the ban on collecting SOA forms at educational events. For example, as part of its previous reasoning, CMS stated that it was concerned that beneficiaries may feel uncomfortable refusing to fill out an SOA form, or that they may feel obligated to provide this information in exchange for attending an educational event. Upon reconsideration, CMS now recognizes that these concerns regarding beneficiary pressure appear to be outweighed by the importance of maximizing beneficiary access to information on available plan options, which could be accomplished by allowing the collection of SOA forms at educational events. In addition, as previously mentioned, there are also beneficiary protections in place should a beneficiary make an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics.

Thus, CMS proposes to modify §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D) to permit plans and agents/brokers holding or participating in educational events with beneficiaries to make available and receive SOA forms at those same educational events. Specifically, at paragraph (c)(1)(ii)(D) in both §§ 422.2264 and 423.2264, CMS proposes to replace the phrase "Cards, but not including Scope" with the phrase "Cards and Scope" so that it reads "including Business Reply Cards and Scope of Appointment forms." CMS notes that the remaining distinctions and inherent beneficiary protections between educational events as required under §§ 422.2264(c)(1) and 423.2264(c)(1) and marketing or sales events as required under §§ 422.2264(c)(2) and 423.2264(c)(2) remain.

In summary, CMS is proposing to modify §§ 422.2264(c) and 423.2264(c) to improve rules regarding beneficiary outreach and §§ 422.2274(b)(3), 423.2274(b)(3), 422.2274(c)(9)(ii), and 423.2274(c)(9)(ii) to add specificity and clarify policy in conjunction with the primary proposals at §§ 422.2264(c) and 423.2264(c). These primary proposals include: (1) allowing a marketing event to directly follow an educational event in the same location; (2) allowing a personal marketing appointment to occur at any point following completion

of an SOA form; and (3) allowing the SOA form to be collected from beneficiaries at educational events. CMS's proposed regulatory changes would remove current rules on the time and manner of beneficiary outreach, reduce burden on beneficiaries, plans, and agents/brokers, foster a convenient, beneficiary-friendly experience in the enrollment decision-making process, and ensure consistency and clarity in the regulatory text.

These proposals are not expected to have any economic impact on the Medicare Trust Fund, nor are they expected to have any negative impacts based on capital investments associated with the requirements that CMS is proposing to remove. CMS solicits comments on these proposed amendments to §§ 422.2264(c), 423.2264(c), 422.2274(b)(3), 423.2274(b)(3), 422.2274(c)(9)(ii), and 423.2274(c)(9)(ii), including on the accuracy of assumptions regarding information collection requirements. CMS thanks commenters in advance for their feedback.

G. Relaxing the Restrictions on Language in Advertising
(§§ 422.2262(a)(1)(i), 422.2262(a)(1)(ii), 423.2262(a)(1)(i), and 423.2262(a)(1)(ii))

In the Medicare and Medicaid Program; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (86 FR 5864), hereinafter referred to as the January 2021 final rule, CMS codified 42 CFR 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii), which prohibited MA organizations and Part D sponsors from making unsubstantiated statements, except when used in logos or taglines. Prior to the January 2021 final rule, this requirement was in the Medicare Communications and Marketing Guidelines (MCMG). In the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (88 FR 22120), hereinafter referred to as the April 2023 final rule, CMS updated §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) to prohibit MA organizations and Part D sponsors from using superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the marketing or communications material where the superlative is being used. CMS finalized this current requirement

asserting that, without the updated requirement, a beneficiary may have no knowledge of how the superlative is determined, which may mislead the beneficiary into believing a statement that is not accurate. At the time, CMS noted that providing current, reliable, and valid data as the basis for superlatives is critical for beneficiaries to review the data themselves (88 FR 22238).

When CMS first codified §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) in the January 2021 final rule, CMS explained that the policies being codified were not new to MA organizations and Part D sponsors as they were already included in the MCMG, on which the industry heavily relied at that time (86 FR 5981). After years of implementation and oversight, including one revision to the requirement, CMS now believes the current restrictions regarding use of superlatives at §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) are unnecessary as, per §§ 422.2262 and 423.2262, MA organizations and Part D sponsors are already broadly prohibited from providing beneficiaries marketing and communications materials that are misleading, confusing, or materially inaccurate. Although CMS is proposing to remove the prohibition on the use of superlatives, MA organizations and Part D sponsors would still be required to ensure that all statements, including superlatives, included in marketing and communications materials do not mislead, confuse, or provide materially inaccurate information to current or potential beneficiaries. CMS will continue to review materials as described at §§ 422.2261 and 423.2261, and may request data, reports, or other documentation that supports the MA organization or Part D sponsor's statements in these materials either as a part of the formal review process or based on beneficiary complaints after the materials are actively being used. If finalized, CMS would continue to encourage MA organizations and Part D sponsors to make available to beneficiaries and the public the data, reports, or other documentation that supports the superlative to promote informed enrollment decisions.

Sections 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) were intended to strengthen protections for beneficiaries to ensure they had access to all necessary information needed to make an informed enrollment decision. However, because §§ 422.2262 and 423.2262 already broadly prohibit misleading, confusing, and inaccurate marketing and communications materials, CMS believes that removing

§§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) will not affect the existing beneficiary protections, which will still be in effect, but will reduce the administrative burden for all parties. Although removing §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) does not remove the prohibition on providing misleading, confusing, or materially inaccurate information to beneficiaries, it does remove the requirement for MA organizations and Part D sponsors to reference supporting documentation or data directly in the material. CMS notes, however, that if this proposed change to CMS's regulations is finalized, MA organizations and Part D sponsors can still choose to make data available to beneficiaries as they determine appropriate, which may reduce the administrative burden.

CMS will continue to review applicable materials to ensure they do not provide misleading, confusing, or materially inaccurate information to beneficiaries. To aid CMS in determining if a material is misleading, confusing, or materially inaccurate; in some instances, it may expedite the review process if the MA organization or Part D sponsor provides supporting documentation when submitting marketing materials that include the use of superlatives. Moreover, when the Agency is investigating a material based on a complaint that it was misleading, confusing, or materially inaccurate, CMS may request the plan provide documentation that supports the superlative, per the Agency's oversight authority at §§ 422.504(f)(2) and 423.505(f)(2).

For example, quantifiable superlatives such as "highest rated providers in Chester County," "largest provider network in Florida," or "highest rated plan in Virginia" would be acceptable if this proposed rule is finalized. Further, MA organizations and Part D sponsors must be able to factually support such superlatives through data, surveys, studies, or other type of information, and when requested, provide that information to CMS. In addition, when including superlatives based on older data, to ensure that they are not misleading or confusing, MA organizations and Part D sponsors should indicate the year or in some way show the statement is based on data older than the current or prior contract year. For example, the use of a superlative such as "The most popular Medicare Prescription Drug plan in Montgomery County in 2023" would be acceptable if this proposed rule is finalized. Conversely, CMS would generally find the same statement to be misleading if the date was missing.

CMS recognizes that not all superlatives can be quantified or reasonably measured. For example, the use of superlatives such as "our plan cares about you the most" and "we have the most dedicated providers in our network." Both examples would be permissible if this proposed rule is finalized, and CMS would not expect MA organizations or Part D sponsors to provide supporting documentation as a part of submission, nor would the agency request such information as a part of a complaint investigation.

Consistent with Executive Order 14267,⁵⁵ Reducing Anti-Competitive Regulatory Barriers, issued on April 9, 2025, CMS believes that removing the prohibition on the use of superlatives and underscoring the continued requirement of not misleading, confusing, or providing inaccurate information to beneficiaries will likely promote competition as this revision provides more opportunities for MA organizations and Part D sponsors to innovate while simultaneously protecting beneficiaries' access to accurate materials to help with their enrollment decisions.

For the reasons discussed, CMS proposes to delete current paragraphs at §§ 422.2262(a)(1)(ii) and (a)(1)(ii)(A), and 423.2262(a)(1)(ii) and (a)(1)(ii)(A) in their entirety to remove the prohibition of using superlatives in marketing and communications materials without providing supporting documentation. With this revision, CMS will renumber current paragraphs §§ 422.2262(a)(1)(iii)–(xix) and 423.2262(a)(1)(iii)–(xviii).

Consistent with Executive Order 14192,⁵⁶ Unleashing Prosperity Through Deregulation, issued on January 31, 2025, CMS also proposes deleting the current paragraphs at §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), which reiterate the prohibition on MA organizations and Part D sponsors providing misleading and inaccurate information to beneficiaries. This is a technical change that would remove the duplication of §§ 422.2262 and 423.2262, which already require MA organizations and Part D sponsors to not provide misleading, confusing, or materially inaccurate information to current and potential beneficiaries.

CMS welcomes comments on the proposed changes to §§ 422.2262(a)(1)(i) and (ii) and 423.2262(a)(1)(i) and (ii),

and thanks commenters in advance for their feedback.

H. Third-Party Marketing Organization (TPMO) Oversight: Revising the Record Retention Requirements for Marketing and Sales Call Recordings (§§ 422.2274(g)(2) and 423.2274(g)(2))

CMS is proposing to revise the marketing and sales recording requirements at 42 CFR 422.2274(g)(2) and 423.2274(g)(2). Consistent with the 10 year record retention requirements and access to records requirements described in §§ 422.504(d) and (e)(1)(iv) and §§ 423.505(d) and (E)(1)(iv), MA Organizations and Part D sponsors are expected to retain the sales and marketing call recordings described in §§ 422.2274(g)(2) and 423.2274(g)(2) for 10 years. CMS is proposing to update §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to reduce the amount of time that MA Organizations and Part D sponsors are required to retain recordings of marketing and sales calls to 6 years, while maintaining the requirement that enrollment records be retained for 10 years, as required under §§ 422.504(e)(1)(iv) and 423.505(e). This proposal modifies only the record retention requirements for the marketing and sales portions of calls at 42 CFR part 422, subpart V and Part 423, Subpart V. CMS has long required enrollment records to be maintained for 10 years and this proposal does not remove applicable enrollment documentation and retention requirements set forth in other regulations, specifically the requirement to file and retain enrollment forms as required in §§ 422.60(c)(2), 422.504(e)(1)(iv) and 423.505(e)(1)(iv). To meet enrollment documentation requirements for enrollments that occur over the phone, plans would still be required to record the enrollment portion of the call, as the recording in this instance serves as the enrollment form and provides proof that the beneficiary attested to their intent to enroll in accordance with § 422.60(c)(2) and the Medicare Managed Care Manual, Chapter 2, Medicare Advantage Enrollment and Disenrollment, Section 40.1.3. The enrollment portion of the call begins when the beneficiary is advised that they are completing an enrollment request, after which they provide the information as required by the enrollment form and attest to their intention to enroll.

As a part of the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the

⁵⁵ <https://www.federalregister.gov/documents/2025/04/15/2025-06463/reducing-anti-competitive-regulatory-barriers>.

⁵⁶ <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Final Rule (hereafter referred to as the May 2022 final rule) (87 FR 27704), CMS finalized regulations at §§ 422.2274(g)(2) and 423.2274(g)(2) regarding plan oversight of Third-Party Marketing Organizations (TPMOs). Under these regulations, MA organizations and Part D sponsors must have certain requirements in their contracts, written arrangements, and agreements with TPMOs, or between the TPMO and MA organization or Part D sponsor's first tier, downstream, and related entities (FDR). In §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii), CMS finalized the requirement that an MA organization or a Part D sponsor's contract, written arrangement and/or agreement with the aforementioned entities must ensure that all calls with beneficiaries are recorded in their entirety. In addition, in order to ensure compliance with the 10-year record retention and access to records requirements described in §§ 422.504(d) and (e)(1)(iv) and § 423.505(d) and (e)(1)(iv), MA organizations and Part D sponsors are expected to retain the sales and marketing call recordings described in §§ 422.2274(g)(2) and 423.2274(g)(2) for 10 years.

Following the finalization and implementation of the May 2022 final rule, CMS received questions regarding retention requirements for recorded calls, as MA organizations and Part D sponsors were unsure if calls regarding marketing, sales, and enrollment were subject to the 10-year record retention requirements at §§ 422.504(d) and 423.505(d). CMS also received questions about the scope of "all calls" for recording purposes, including if the recording requirement extended to calls that merely set an appointment with a potential enrollee, calls to enrollees to confirm welcome packets were received, and other non-marketing or non-sales calls to prospective enrollees. CMS notes that the May 2022 final rule did not provide exceptions or otherwise establish a more defined boundary for the type of call that was subject to recording and retention. To rectify any potential unintended consequences stemming from the standard that CMS codified in the May 2022 final rule, CMS issued the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program; Medicare Cost Plan Program, and Programs of All-Inclusive Care for the

Elderly Policy Final Rule (hereafter referred to as the April 2023 final rule) (88 FR 22120), to address the requirement that all calls be recorded and retained. In the April 2023 final rule, CMS modified §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to require only the recording of marketing, sales, and enrollment calls, including the audio portion of calls via web-based technology. The implementation of this revised and less burdensome call recording requirement was to ensure the necessary calls were recorded and available for oversight and monitoring while still reducing some level of burden on plans.

CMS has continued to oversee and monitor agent and broker behavior by reviewing call recordings to determine compliance. In addition to CMS, other governmental entities (e.g., Department of Justice) have relied on call recordings for investigations. CMS has requested call recordings based on complaints from CMS's Complaint Tracking Module (CTM). The requested recordings were chosen based on the severity of the allegations in the complaint in the CTM and used to determine if the merit of the claims against the agent or broker. The outcome of CMS's review of the marketing and sales portion of the call recordings has been mixed. In some instances, the recordings did not support the beneficiary's complaint as detailed in the CTM. In other instances, the complaints were substantiated by the recording. These reviews have shown examples where agents and brokers fail to provide sufficient information for a beneficiary to make an informed decision or the information provided by the agent or broker is inaccurate. For reviewed complaints that are substantiated, CMS has notified the MA organization or Part D sponsor of the agency's findings and requested the organization review the results and take appropriate action against the agent, broker, or TPMO. MA organizations and Part D sponsors have responded to CMS's findings with actions such as retraining or discontinuing contracts with certain entities.

MA organizations and Part D sponsors are responsible for ensuring all downstream entities meet CMS's requirements. There are over 68 million Medicare beneficiaries, of which 51.1 percent are enrolled in MA and other health plans.⁵⁷ Of the approximately 34 million beneficiaries enrolled in an MA plan or other health plan, 31 percent use

agents to assist with plan choices,⁵⁸ resulting in 10,540,000 beneficiaries discussing plan options with agents annually. Each year, only three out of every ten beneficiaries compare plans during Medicare's Annual Election Period,⁵⁹ resulting in approximately 3.1 million beneficiaries using agents or brokers to review their plan choices. Based on these data, CMS conservatively estimates that MA organizations, Part D Sponsors, and their TPMOs must record hundreds of thousands of calls each year to comply with these regulatory requirements, resulting in millions of calls being subject to the 10-year retention requirement.

CMS recognizes the cost and burden of these requirements. CMS has received comments from industry groups noting the costs associated with recording and retaining the marketing and sales portion of calls. Audio call files are large, taking a substantial amount of data storage, especially when the record retention requirement is to store these calls for 10 years. In addition, to the cost of maintaining these calls, CMS is highly unlikely to review calls past the 6-year mark. To best address marketing complaints, the review of calls typically needs to be much closer to the timeframe of the actual complaint. Reviewing complaints that are 10 years old may result in the discovery of issues that are irrelevant and that will not result in identifying current issues that affect beneficiaries. Because of these reasons, CMS is proposing to reduce the timeframe for the retention of the marketing and sales portion of calls from a 10-year requirement to a 6-year requirement. If finalized, this revised retention requirement would also apply to currently retained call recordings, meaning that any marketing and sales portion of calls older than 6 years that are currently being retained would no longer need to be retained.

CMS believes a 6-year record retention requirement for the marketing and sales portion of calls is sufficient for the purpose of enabling CMS review of agent and broker behavior and balances the need for appropriate oversight while also providing consideration of the burden imposed by record retention. It is helpful to CMS to review the marketing and sales portion of audio recordings when the Agency receives complaints from beneficiaries related to being misled into choosing a plan and

⁵⁸ <https://www.medpac.gov/wp-content/uploads/2024/08/Medicare-agents-MedPAC-03.25sec.pdf>.

⁵⁹ <https://www.kff.org/medicare/issue-brief/nearly-7-in-10-medicare-beneficiaries-did-not-compare-plans-during-medicare-open-enrollment-period/>.

⁵⁷ <https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment>.

then enrolling in that plan. The marketing and sales portion of these recordings is most useful when it is recent and permits CMS to provide timely feedback to MA organizations and Part D sponsors, so they may, in turn, quickly address any compliance issues that are identified by CMS review.

While proposing a revised 6-year record retention requirement for the marketing and sales portion of calls, CMS is also considering several other alternatives described below and CMS might finalize a policy that includes, but is not limited, to the specific alternatives discussed below. CMS is considering alternatives based on the cost and burden of recording and storing calls when CMS only reviews a few hundred calls each year.

One alternative to the proposed 6-year retention requirement is to reduce the 10-year retention requirement for the marketing and sales portion of calls to a 3-year retention requirement. This alternative would also further decrease existing burden and costs on MA organizations and Part D sponsors but would provide both CMS and other oversight organizations with a shorter lookback period. A shorter lookback period could make it more challenging to identify longer-term trends, including potential trends associated with TPMOs. However, a 3-year retention requirement would result in a more significant decrease in burden as compared to the proposed 6-year retention requirement.

CMS is also considering alternatives such as whether audio recordings of the marketing and sales portion of calls are necessary for record retention purposes or whether the ability to review agent and broker behavior could be achieved via other, less expensive means. Specifically, CMS is considering whether permitting written retention of the marketing and sales portion of calls (*i.e.*, a transcript) in lieu of retaining audio recordings of such calls, or a hybrid approach that requires audio recordings for 3 years followed by written retention for remainder of the retention period would be sufficient to achieve the purpose articulated by CMS within this proposal. An important factor to this alternative is the ability of current technology to automate the transcription with sufficient accuracy. CMS believes these transcripts might still provide CMS with enough ability to review interactions between beneficiaries and agents and brokers to identify non-compliance similar to the review of audio recordings. On the other hand, transcripts would not capture the tone by which the agent or broker interacted with the beneficiary. Either

way, the data storage costs of retaining transcripts may be less than the data storage costs of audio recordings, further reducing burden if new costs from automated transcription did not outweigh those savings.

Finally, based on the mixed findings from the review of call recordings, CMS is also considering, as an alternative, whether maintaining a recording, either audio or otherwise, of the marketing and sales portion of calls is necessary at all. The results of the review of these portions of calls, as identified earlier in this proposal, have provided examples that agents and brokers do not always provide accurate and truthful information. Conversely, in other instances, the call recordings offer a way to refute beneficiary complaints, such as those filed through 1-800-MEDICARE. However, by eliminating these requirements, CMS and other oversight organizations would not have the ability to directly review agent and broker behavior to ensure beneficiaries select a plan that best meets their needs. CMS acknowledges there are differences between MA, Part D, Marketplace, Medicaid, and commercial insurance, however, CMS notes the elimination of recording the MA and Part D marketing and sales portion of calls would result in more parity with the requirements of these programs.

To reiterate, CMS is specifically seeking comment on: (1) the appropriate duration of the recording retention requirement, *i.e.*, 3 years, 6 years, or other timeframes, for the marketing and sales portion of calls; (2) alternative means of recording the marketing and sales portion of calls, such as transcription, in lieu of requiring an audio recording, including input on other technologies to aid in capturing the interaction between a TPMO and a Medicare beneficiary; (3) whether the agency should completely remove the requirement to record the marketing and sales portion of calls, including what alternative means of oversight the agency could implement to ensure an appropriate level of oversight; and (4) the impact of proposed and alternative requirements on beneficiaries. CMS also welcomes other options for reducing the burden and costs associated with these requirements. In providing alternatives, CMS is also seeking the savings attributed to each of the alternatives. We are also seeking rationale, including the accuracy of transcriptions, for each alternative.

CMS solicits comments on all aspects of this proposal and may consider alternatives and other revisions based on the comments received, including, but not limited, to the specific

alternatives discussed above, which, based on comments, may be finalized rather than the proposal.

I. Rescinding the Requirement for the Notice of Availability (§§ 422.2267(e)(31) and 423.2267(e)(33))

The Notice of Availability of language assistance services and auxiliary aids and services (NoA) material, formerly known as the Multi-language insert (MLI), required at 42 CFR 422.2267(e)(31) and 423.2267(e)(33), has been modified in conjunction with changes to the Health and Human Services Office for Civil Rights (OCR) language assistance notification requirements (currently at 45 CFR 92.11), implementing section 1557 of the Affordable Care Act (ACA), 42 U.S.C. 18116. Currently, CMS's NoA requirements are closely aligned with and broadly duplicate OCR's NoA requirements. On March 1, 2025, Executive Order (E.O.) 14224 was issued: "Designating English as the Official Language of The United States" (hereinafter referred to as E.O. 14224).⁶⁰ E.O. 14224 designates English as the official language of the United States and includes the revocation of E.O. 13166 of August 11, 2000 (Improving Access to Services for Persons with Limited English Proficiency). On January 31, 2025, E.O. 14192 was issued: "Unleashing Prosperity Through Deregulation" (hereinafter referred to as E.O. 14192).⁶¹ E.O. 14192 describes the Administration's policy goals to promote prudent financial management and alleviate unnecessary regulatory burdens. Section 2 of E.O. 14192 states that "it is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people." Lastly, a recent memorandum from the Office of the Attorney General, released on July 14, 2025,⁶² which provides guidance for compliance with E.O. 14224, introduces additional uncertainty regarding the future of language assistance requirements. To ensure consistency and reduce the risk of misalignment, CMS believes it is prudent to defer to OCR as to how this guidance will impact language assistance and auxiliary aid and service

⁶⁰ <https://www.whitehouse.gov/presidential-actions/2025/03/designating-english-as-the-official-language-of-the-united-states/>.

⁶¹ <https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/>.

⁶² <https://www.justice.gov/opa/pr/justice-department-releases-guidance-implementing-president-trumps-executive-order>.

requirements throughout the programs under HHS's purview.

CMS's requirements under §§ 422.2267(e)(31) and 423.2267(e)(33) currently duplicate OCR requirements at 45 CFR 92.11. To ensure clarity, minimize administrative burden, and limit confusion for MA organizations and Part D sponsors regarding language assistance and auxiliary aids and services notification requirements, CMS is proposing to eliminate the NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) and to defer to OCR's oversight and management of any requirements related to language assistance and auxiliary aids and services notifications. This would mitigate the potential for future misalignment and the need for additional modifications to CMS's requirements as policy evolves.

CMS historically has looked to OCR's language requirements when promulgating regulations for the MA and Part D programs. On May 18, 2016, OCR published the Nondiscrimination in Health Programs and Activities final rule (81 FR 31376), hereinafter referred to as the "2016 section 1557 final rule," implementing the requirement that all covered entities—any health program or activity that receives Federal financial assistance—include taglines with all "significant communications." On June 19, 2020, the Department of Health and Human Services (Department) published a new section 1557 final rule, "Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority," hereinafter referred to as the 2020 section 1557 final rule (85 FR 37160), rescinding the 2016 section 1557 final rule's tagline requirements (84 FR 27860).

To address the gap after the rescission of OCR's tagline requirements in the 2020 section 1557 final rule, CMS finalized an MLI requirement in the "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" final rule (87 FR 27704), hereinafter referred to as the "May 2022 final rule." CMS, at §§ 422.2267(e)(31) and 423.2267(e)(33), required the MLI to have a CMS-provided standardized tagline in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

Additionally, the MLI required that MA organizations and Part D sponsors include additional languages in the plan's service area that met the 5 percent service area threshold, as required under §§ 422.2267(a)(2) and 423.2267(a)(2). Sections 422.2267(a)(2) and 423.2267(a)(2) require that, for all required materials and content under §§ 422.2267 and 423.2267, MA organizations and Part D sponsors must, "for markets with a significant non-English speaking population, be in the language of these individuals." Specifically, MA organizations and Part D sponsors "must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area."

On August 4, 2022, OCR proposed a new rule, Nondiscrimination in Health Programs and Activities (hereinafter referred to as the "2022 proposed rule") for section 1557 of the ACA (87 FR 47824), to require covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities at no cost using a NoA and requiring that the NoA be provided in English and at least in the 15 most common languages spoken by individuals with limited English proficiency in the relevant State or States, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications."⁶³

To ensure consistency, following OCR's 2022 proposed rule, CMS finalized the current NoA in the "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)" final rule (89 FR 30448), hereinafter known as the "April 2024 final rule." In this rule, CMS renamed the required document from the MLI to the Notice of availability of language assistance services and auxiliary aids and services at §§ 422.2267(e)(31) and 423.2267(e)(33) to align with OCR's language. Additionally, the notice was recategorized from a standardized communications material to a model

⁶³ The proposed rule was finalized, with minor modifications on May 6, 2024, (89 FR 37522), creating the requirements for the notice of the availability of language assistance services and auxiliary aids and services at 45 CFR 92.11.

communications material, requiring plans to include in the notice that, at a minimum, the MA organization or Part D sponsor provide language assistance services and appropriate auxiliary aids and services free of charge (89 FR 30534). The updated NoA also updated the language criteria to align with OCR's proposed language at the time. To align with OCR, CMS finalized the requirement for plans to provide the NoA "in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication." CMS maintained the requirement that the NoA also include any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area, provided it was beyond the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area. This update resulted in the potential for MA plans and Part D sponsors to develop a NoA with more than 15 languages, exceeding OCR's requirements.

While currently, OCR's and CMS's requirements are mostly aligned, CMS notes minor differences in the language of the current regulations. The OCR NoA requirement applies to the "State or States in which a covered entity operates" which is broader than CMS's requirement. CMS's NoA requirement applies to the "State or States associated with the plan's service area" which CMS defined as the plan benefit package level. Additionally, CMS requires the NoA to be included on all CMS required materials at §§ 422.2267(e) and 423.2267(e), whereas OCR's language regarding where the NoA should be placed (45 CFR 92.11(c)(5)) is less specific, though its guidance still aligns with many of CMS's required materials.

As discussed in the April 2024 final rule, the ACA (42 U.S.C. 18116(c)) provides that, except where otherwise provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* (race, color, or national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.* (age), or section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits

of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance); any program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act.

In the April 2024 final rule, CMS cited discussions from the May 2022 final rule, that “solely relying on the requirements delineated in the 2020 section 1557 final rule for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and Part D programs and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive their Medicare benefits through these plans and who are enrolled in these plans” (89 FR 30529). At the time, CMS took the position that “informing Medicare beneficiaries that interpreter services are available is essential to realizing the value of our regulatory requirements for interpreter services” (89 FR 30529). CMS further explained that through additional insights “regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries the materials required under §§ 422.2267(e) and 423.2267(e) were vital to the beneficiary’s decision-making process” (87 FR 27821). CMS also cited complaint tracking module (CTM) cases in the Health Plan Management System (HPMS) related to “language” and found a pattern of beneficiary confusion stemming from not fully understanding materials based on a language barrier.

In the April 2024 final rule, CMS also explained that updating the NoA requirements in Parts C and D would help align with the Medicaid requirement under § 438.10(d)(2), in which “States must require Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and primary care case management programs to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State explaining the availability of oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services in the State” (89 FR 30529). Therefore, CMS finalized NoA requirements that also aligned with Medicaid materials requirements, such

as updating the NoA to require the 15 most common languages in the State rather than the 15 most common languages nationally (89 FR 30529).

While CMS’s and OCR’s current requirements are now mostly aligned, CMS is concerned that the duplicative nature of these requirements may potentially result in additional regulatory updates, and corresponding burdens as policy evolves. Because CMS and OCR regulatory schedules vary, the potential differences in requirements can be confusing and burdensome to MA organizations and Part D sponsors who are subject to CMS requirements and the broader OCR requirements as covered entities. Additionally, uncertainty regarding broad changes to language assistance and notification requirements, or how OCR may modify their requirements as policy evolves may result in additional confusion, administrative burden and potential for misalignment of the NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33). Eliminating the NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) will ensure consistency and clarity for covered entities as these requirements will be addressed centrally by OCR. CMS notes that dual eligible special needs plans would still be subject to any notice requirements that may be included in the State Medicaid agency contract or State statute for Medicaid as applicable. Overall, CMS’s position is that eliminating the duplicative nature of OCR’s and CMS’s regulatory requirements supports the principles set forth in E.O. 14192 by promoting prudent financial management and alleviating unnecessary regulatory burdens.

In summary, this proposal will reduce administrative burden on CMS, MA organizations and Part D sponsors by eliminating duplicative requirements. CMS is not scoring this provision in the COI section as CMS believes there will be no burden impacts for this provision. In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund. CMS solicits comments on the agency’s proposed amendments.

J. Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits

1. Background

Section 423.505(e) authorizes CMS to evaluate, through audit, inspection, or other means, the appropriateness of services furnished to Medicare enrollees under a Part D contract. Consistent with this authority, CMS conducts Part D

prescription drug event (PDE) record review audits under the Center for Program Integrity (CPI) that identify improper PDE records paid under the Medicare Part D benefit, herein referred to as Part D program integrity PDE record review audits, including instances in which the drug, item, or service does not meet the definition of a covered Part D drug under section 1860D–2(e) of the Act. As part of these audits, CMS identifies PDE records that it believes are potentially improper, and plan sponsors submit supporting documentation to rebut this finding and demonstrate that the drug, item, or service was appropriate for coverage under the Medicare Part D program. If CMS determines, based on a review of this documentation, that Medicare Part D rules and regulations were not met and therefore the PDE is improper, CMS notifies the Part D plan sponsor to submit PDE deletion or adjustment records for the associated record(s) in accordance with § 423.325(a)(2) and subregulatory guidance. The deleted PDE records result in savings to the Medicare Trust Fund when the PDE record for a given plan year is included in that plan year’s global reopening, described at § 423.308 and § 423.346(a)(2).

Currently, Part D plan sponsors have one opportunity to submit documentation demonstrating that a PDE record was appropriate for coverage under the Part D program, which occurs during the audit itself. Because there is currently no process for Part D plan sponsors to further appeal determinations that a PDE record was improper, we propose to establish a three level appeals process for Part D program integrity PDE record review audits. Specifically, we propose to amend 42 CFR part 423 subpart Z, which currently outlines the Recovery Audit Contractor (RAC) Part D appeals process, to include any Part D program integrity PDE record review audits. We also propose several conforming revisions to achieve alignment and streamlining of the Part D program integrity PDE record review audit appeals processes. Under this revised appeals process, Part D plan sponsors would receive an audit close out letter including: (1) an explanation of the drug, item, or service under audit; (2) a high-level overview of improper and proper PDE record counts; (3) an attached PDE level record file denoting improper and proper PDE records; (4) requirements for the submission of deletion records or adjustment records for the PDEs determined to be improper; and (5) instructions on how the Part D

plan sponsor may appeal the findings. There would be no minimum threshold for an appeal at any level.

2. Appeals Process

In this rule, we are proposing to codify at 42 CFR part 423 subpart Z changes to the existing RAC appeals process to include any CMS Part D program integrity PDE record review audits. To reflect the proposed expansion of the appeals process, we propose to revise the regulatory text title of subpart Z from “Recovery Audit Contractor Part D Appeals Process” to “Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits”. This change will establish an appeals process for Part D plan sponsors to appeal findings for Part D program integrity audits conducted by CMS that review PDE records for appropriateness.

Currently, 42 CFR part 423 subpart Z sections 423.2600 to 423.2615 describe what may or may not be subject to appeal and the processes for each of the three levels of appeal, which include: (1) request for reconsideration, (2) hearing official review, and (3) review by the Administrator. To align with the changes being proposed concurrently under subpart Z, these regulations would likewise remove the mention of the RACs specifically, as the appeals process will include any Part D program integrity audits that review PDE records for appropriateness.

Furthermore, the proposed modifications would establish review timeframes for the different review entities at each level of appeal. The RAC Part D payment audits recovered improper payments from Part D plan sponsors through the monthly capitation payment, and therefore, could recover funds at any time without constraints. As such, the current regulatory text for the RAC audit appeals did not have a need to require that the independent reviewer make their decision within a certain timeframe. However, current Part D program integrity PDE record review audits require the plan sponsors to submit deletion records to CMS for all PDE records deemed improper during audit, in accordance with § 423.325(a)(2) and prior to the global reopening for any given plan year, to ensure the integrity of the Medicare Trust Fund. For these reasons, we believe it is necessary to provide timeframes for decisions to be made at each appeal level. We believe that three levels of appeal, with review timeframes, would allow sufficient opportunity for Part D plan sponsors to appeal a determination and ensure that

timely and accurate determinations are made consistent with the rules and regulations of the Part D program.

a. Payment Appeals (§ 423.2600)

The current payment appeals language at § 423.2600 describes for the Part D plan sponsor what is or is not considered appealable during a RAC payment audit. To align with the broadened scope of subpart Z, as proposed, we are proposing to also amend the language describing what is or is not considered appealable to reflect the scenarios that apply to Part D program integrity PDE record review audits. As such, we propose to modify the existing regulatory language at § 423.2600 to state Medicare Part D plan sponsors may appeal program integrity PDE prescription drug event record review audit determinations. We propose to add a new paragraph (a) to § 423.2600, which would identify the issues that may be appealed through the audit appeals process. Specifically, under (a) Issues eligible for appeal, we propose to add paragraph (a)(1) to state CMS’s application of Part D policy(ies). Part D policy(ies) refer to any Part D sponsor requirement from CMS outlined in the Code of Federal Regulations CFR, CMS manuals, or other communications from CMS. Proposed paragraph (a)(2) would specify that Part D sponsors may appeal factual or data errors. Examples of appealable issues at (a)(1) or (a)(2) would include: (1) a determination that a drug, item or service was excluded from coverage under the Medicare Part D program; or (2) a determination that a Medicare Part D payment was a duplicate payment. Errors of this nature would be appealable given there would be documentation for the reviewers to review to ensure that the payment was proper under the Medicare Part D benefit. The independent reviewer would review the documentation to determine and ensure that the payment was proper and in accordance with Medicare Part D policies. Furthermore, the independent reviewer may also determine, based on documentation submitted, whether the error resulted from actions made by CMS.

We propose to further amend § 423.2600 by adding a new paragraph (b), which would identify issues ineligible for appeal. Proposed paragraph (b)(1) would specify that Part D plan sponsors may not appeal the failure to submit documentation in the timeframes specified by CMS during the audit. Failure to submit documentation would not be appealable, given the plan sponsor has the opportunity to provide the documentation to CMS for review within a specified audit timeframe.

Historically, during Part D program integrity PDE record review audits, the audit timeframes are extended due to the documentation lacking specific information needed to evaluate the PDE records appropriateness. This greatly affects the overall length of the audit and causes undue burden on both the plan sponsor and CMS. Therefore, CMS is proposing to require that plan sponsors provide documentation in accordance with the provisions in this proposed rule that propose updates at § 423.505, and accordingly, failure to provide this information would result in an improper determination that is not appealable. Providing documentation in accordance with the provisions proposed at § 423.505 will greatly reduce the burden and overall audit timeline for both CMS and Part D plan sponsors, as CMS will not have to request additional information from the plan sponsors. Proposed paragraph (b)(2) would state that Medicare Part D plan sponsors may not appeal the program integrity PDE record review audit methodology. That is, while CMS’s application of Part D policy(ies) and factual or data errors may be appealed, the Part D plan sponsor may not appeal the underlying audit methodology, such as the manner in which data was extracted.

b. Reconsiderations (§ 423.2605)

In existing paragraph (a), we propose to replace the term “demand letter” with the term “close out letter” for consistency with current terminology in CMS’s Part D program integrity PDE record review audits. In existing paragraph (e), we propose to add a timeframe for when the independent reviewer’s decision needs to be decided and communicated to the Part D plan sponsor and CMS. Specifically, we propose to amend the language from “[t]he independent reviewer informs CMS and the Part D plan sponsor of its decision in writing” to “the independent reviewer decides the reconsideration within 60 calendar days after the timeframe for filing a rebuttal has expired, and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.” Adding a timeframe for the independent reviewer’s decision gives CMS the opportunity to ensure that any upheld improper PDE records can be submitted as a deletion record by the plan sponsor within the global reopening timeframe.

c. Hearing Official Review (§ 423.2610)

In the existing regulatory text at § 423.2610, CMS outlines the process for a hearing official review. We propose to

revise paragraph (d)(2)(i), to replace “Part D RAC” with “CMS” for consistency with the changes, discussed previously, regarding the audits to which these appeals processes apply. We propose to revise paragraph (d)(3) to remove the phrase “nor CMS may submit” and replace it with “nor CMS is permitted to submit” to establish stronger verbiage that the submission of new evidence is not permitted by either the plan sponsor or by CMS and will not be considered by the hearing official. In addition, we propose to revise paragraph (e), to replace “60 days” with “60 calendar days after the timeframe for filing a rebuttal has expired,” to be explicit that 60 days refers to calendar days rather than business days. Furthermore, we propose to revise paragraph (f), to replace the existing language that states “§ 423.2610” with “§ 423.2615”, to fix a citation error in the existing regulatory text. The existing text in paragraph (f) refers to the hearing official’s decision being binding unless overturned in the third level of appeal by the CMS Administrator. The Administrator level of appeal is found at § 423.2615 not at § 423.2610, and therefore, the citation needs to be corrected.

d. Review by the Administrator (§ 423.2615)

In the existing regulatory text at § 423.2615, CMS outlines the process for the review by the Administrator. We propose to revise paragraph (b)(2) to remove the phrase “nor CMS may submit” and replace it with “nor CMS is permitted to submit” to establish stronger verbiage that the submission of new evidence is not permitted by either the plan sponsor or by CMS and will not be considered by the Administrator. In existing paragraph (d), we propose to replace “45 days” with “30 calendar days.” Furthermore, in existing paragraph (e), we propose to add a 45-calendar day timeframe for the Administrator to furnish a final decision. Specifically, the regulatory text will be amended to read, “If the CMS Administrator agrees to review the hearing official’s decision, he or she determines, after reviewing the hearing record and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and CMS within 45 calendar days after the timeframe for filing a rebuttal has expired.” Both reducing the timeframe for the Administrator to decide if they will

review the case and adding a timeframe for furnishing a final decision would help ensure that any upheld improper PDE records can be submitted as a deletion record by the plan sponsor within the global reopening timeframe. The timeframes proposed are critical to ensure the appeals process is completed by the PDE submission deadline for the global reopening. Completion within the global reopening timeframe enables CMS to properly oversee the Medicare Part D program by ensuring CMS has accurate, complete, and truthful claims data, in accordance with § 423.505(k)(3), and to protect the integrity of the Medicare Trust Fund.

K. Prescription Drug Event Submission Timeliness Requirements (§ 423.325)

1. Background

CMS codified its requirements for the timely submission of prescription drug event (PDE) records at 42 CFR 423.325 in the final rule titled “Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” which appeared in the April 15, 2025, **Federal Register** (hereinafter referred to as the April 2025 final rule). In that rule, we described the General PDE Submission Timeliness Requirements at § 423.325(a) and the Selected Drugs PDE Submission Timeliness Requirement at § 423.325(b).

Under the General PDE Submission Timeliness Requirements, a Part D sponsor must submit an initial PDE record within 30 calendar days from the date the Part D sponsor receives the claim, submit adjustment or deletion PDE records within 90 calendar days of the discovery or notification of an issue requiring a change to the previously submitted PDE records, and resolve rejected PDE records within 90 calendar days of the rejection. The General PDE Submission Timeliness Requirements apply unless the Selected Drugs PDE Submission Timeliness Requirement is applicable.

In this rule, we propose to modify the General PDE Submission Timeliness Requirements by modifying existing § 423.325(a)(3) related to the submission of PDE records to resolve a rejected PDE record. Under the current rule, Part D sponsors must submit a revised PDE record to resolve a PDE record that CMS rejected through the PDE editing process within 90 calendar days of the receipt of rejected record status from CMS. We recognize that submission of a revised PDE record is not always appropriate.

As the regulation is currently written, a Part D sponsor may not be able to comply with the current rule under various scenarios. Therefore, we propose to set forth new requirements related to the resolution of rejected PDE records.

a. Rejected PDE Records

Part D sponsors submit PDE records to CMS through the Drug Data Processing System (DDPS). The DDPS performs checks on the data to validate and help ensure its accuracy, including checks for missing and invalid information, beneficiary eligibility, and calculation checks on costs and payment fields.⁶⁴ These checks can result in the PDE data being accepted or rejected by the DDPS. Consistent with our long-standing guidance⁶⁵ and pursuant to § 423.325(a)(3), Part D sponsors must resolve those rejections within 90 calendar days, that is, resubmit corrected PDE records to CMS within 90 calendar days of receiving the rejection.

CMS recognizes there are a range of situations where it might be inappropriate to submit a revised PDE record after receiving a rejection. For example, if a rejected record is no longer associated with a valid claim, it would not be appropriate for the Part D sponsor to submit a corrected PDE record. A valid claim would not exist, for example, if a pharmacy reversed the claim and returned the drug to stock because the beneficiary never obtained the prescription.

Likewise, if the PDE record that was rejected should never have been submitted to CMS in the first instance because the record was contrary to CMS’s requirements, it would not be appropriate to resubmit a PDE record that continues to be contrary to CMS’s requirements. For example, if a PDE record was rejected because the prescriber listed on the applicable claim is on the HHS–OIG’s List of Excluded Individuals/Entities (LEIE) without an applicable waiver, CMS does not expect that the Part D sponsor would resubmit the PDE record if the claim continues to list an excluded prescriber without an applicable waiver.

Given the scenarios described in this Background, it may not be appropriate

⁶⁴ See generally, DDPS Edit Spreadsheet, at [https://www.csscopersations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK-Prescription%20Drug%20Program%20\(Part%20D\)-References](https://www.csscopersations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK-Prescription%20Drug%20Program%20(Part%20D)-References).

⁶⁵ HPMS memorandum, *Revision to Previous Guidance Titled “Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs”*, October 6, 2011, available at <https://www.cms.gov/httpeditcmsgovresearch-statistics-data-and-systemshpmscomputer-data-and-systemshpmsmemos-archive/hpms-memo-qtr1-4>.

to resolve a PDE rejection with submission of a revised PDE record. The submission of a PDE record implies that there was and continues to be a valid claim. Resubmission of a previously rejected PDE record associated with an invalid claim could be harmful to the Part D program. Such data could inadvertently cause problems with the analysis of the rejected data, with no visibility into why such rejected data was never corrected.

In addition, it is not possible for the Part D sponsor to “delete” the rejected PDE record to avoid non-compliance with the requirement when these scenarios arise. This is due to operational constraints. CMS’s DDPS does not allow Part D sponsors to submit PDE deletion records associated with rejected PDE records.

2. Requirements

As explained in the Background, CMS does not always have insight into why a Part D sponsor might not submit a revised PDE record to resolve certain rejected PDE records. Ensuring greater transparency regarding the status of rejected PDE records would enhance CMS’s oversight of Part D sponsors’ compliance with PDE submission timeliness requirements. We propose to modify the existing regulation at § 423.325(a)(3) to account for the scenarios described in the Background, increase transparency, and construct the requirement to account for circumstances where resubmission of PDE records is not appropriate.

We propose that Part D sponsors must submit a PDE record within 90 calendar days from receipt of the rejection and within every 90 calendar days thereafter until a revised PDE record is accepted unless the claim associated with the rejected PDE record is reversed or deleted, or the PDE record is otherwise found to have been submitted in error. We believe that submissions at least once every 90 calendar days will allow CMS to know that the rejected PDE record continues to reflect an active claim that the sponsor believes is valid and for which the sponsor is working to resolve the bases for the PDE rejection. The sponsor is not required to submit revised PDE records at least once every 90 calendar days, if the claim associated with the rejected PDE record is reversed or deleted, or the PDE record is otherwise found to have been submitted in error. This additional information will provide CMS with greater insight into the PDE revision process and ensure that a rejected PDE record must be corrected by the plan sponsor unless it is not appropriate to do so.

CMS believes that it is beneficial for program integrity for the agency to have increased visibility into the processing and progression of revisions of rejected PDE records. This includes ensuring that rejected PDE records that are not resubmitted within 90 days, in accordance with § 423.325(a)(3), are limited to claims that are no longer active and where resubmission is inappropriate (because for example, the pharmacy has since reversed the claim).

We note that since 2011, the vast majority of the PDE records that are rejected are resolved by sponsors within the 90-day timeframe, and in more recent years, nearly all the PDE rejections are resolved within the 90-day timeframe. Therefore, CMS expects no additional costs or savings from the proposed change and is not scoring these requirements in the Regulatory Impact Analysis section. There are no new reporting requirements.⁶⁶ We do not anticipate additional paperwork burden. Therefore, no increase is included in the Collection of Information section.

We welcome feedback on these proposed changes.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (Star Ratings) (§§ 422.164, 422.166, 423.186, and 423.184)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Part C,⁶⁷ more commonly referred to as Medicare Advantage (MA), and Part D plans as part of its responsibility to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act. The Part C and Part D Star Ratings system is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of MA beneficiary rebates under section 1854(b) of the Act. We use multiple data sources based on the collection of different types of quality data under section 1852(e) of the Act to measure the quality and performance of contracts, such as CMS administrative data, surveys of enrollees, and information provided directly from health and drug plans. CMS regulations, including §§ 417.472(j) and (k),

422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data that help beneficiaries compare plans. The methodology for the Star Ratings system for the MA/Part C and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively, and we have specified the measures used in setting Star Ratings through rulemaking. In addition, the cost plan regulation at § 417.472(k) requires cost contracts to be subject to the Parts 422 and 423 MA and Part D Prescription Drug Program Quality Rating System. As a result, the regulatory changes proposed here will apply to the quality ratings for MA plans and cost plans.

We have continued to identify enhancements to the Star Ratings program to ensure it is aligned with the CMS Quality Strategy as that Strategy⁶⁸ evolves over time to increase the health and wellbeing of enrollees. In this proposed rule, we are proposing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set. We also propose to not move forward with the implementation of the Health Equity Index reward and to continue to include the historical reward factor in the Star Ratings methodology. We propose to add additional information about the data available to MA organizations and Part D sponsors during the plan preview periods before each Star Ratings release. We also solicit comments on ways to further simplify and modify the Star Ratings program to further drive improved quality of care, and whether there are ways to streamline the timeline from measure development to implementation. We solicit additional feedback related to Star Ratings in the Request for Information on Future Directions in Medicare Advantage in section XXXX of this proposed rule.

B. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Part C and Part D Star Ratings program. As has been historically operationalized and as described at 83 FR 16533, measure removals are proposed and finalized through rulemaking unless they meet the requirements at §§ 422.164(e)(1) and 423.184(e)(1), which allow for measure removals through the process described

⁶⁶ See OMB 0938–0982, CMS–10174, expiration April 30, 2027 (available at https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202403-0938-002).

⁶⁷ We generally use “Part C” to refer to the quality measures and ratings system that apply to MA plans and cost plans.

⁶⁸ <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy>.

for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. This subregulatory process for measure removal was codified at §§ 422.164(e)(1) and 423.184(e)(1) to allow CMS to remove measures quickly, and without separate rulemaking, in certain circumstances where it is appropriate and necessary to do so. We are proposing language at §§ 422.164(e)(3) and 423.184(e)(3) to clarify our existing policy that removal of measures for any other reasons not stated in paragraph (e)(1) will be proposed and finalized through rulemaking. We are also proposing language at §§ 422.164(e)(2) and 423.184(e)(2) to clarify that removals for the reasons stated in paragraph (e)(1) will either be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act or proposed and finalized through rulemaking. This language would reflect that where one of the bases for measure removal identified in paragraph (e)(1) applies, we would pursue removal using the process that allows for the most expedient notice to MA organizations and Part D sponsors at that time. For example, if a measure steward announces a measure retirement, we would use the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act or rulemaking depending on the timing of the announcement so that we can provide this information as quickly as possible to MA organizations and Part D sponsors.

In the “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” final rule which appeared in the **Federal Register** on April 16, 2018 (83 FR 16532) (“April 2018 final rule”), we stated we are committed to continuing to improve the Part C and Part D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-substantive updates. (See also 83 FR 16534 through 16537.) Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and their specifications) adopted for the Part C and Part D Star Ratings program. CMS

lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued with publication of the Star Ratings.

1. Removing Measures

As the Part C and Part D Star Rating program continues to evolve and align with the measures included in the Universal Foundation,⁶⁹ a strategy to align measures across the agency’s quality and value-based care goals, we propose to simplify and refocus the measure set on clinical care, outcomes, and patient experience of care measures where performance is not topped out and where there is more variation in performance across contracts. Reducing the number of measures would increase the focus on the remaining measures, including those consistent with the Make America Healthy Again (MAHA) initiative, such as Reducing the Risk of Falling and Monitoring Physical Activity. Additionally, reducing the number of measures is consistent with recommendations from MedPAC⁷⁰ and other interested parties that CMS consider having fewer measures in the Part C and Part D Star Ratings program. This is also consistent with the Universal Foundation which attempts, among other things, to focus attention on measures that are meaningful for the health of broad segments of the population and to reduce provider burden by streamlining and aligning measures—in other words, to focus the measure set on clinical care, outcomes, and patient experience of care measures. We initially solicited feedback on simplifying and refocusing the measure set in the Advance Notice of Methodological Changes for Calendar Year (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (“2026 Rate Announcement”),⁷¹ as well as from the Star Ratings Technical Expert Panel (TEP) in October 2024.⁷²

Although the TEP recommended keeping the measure set as large as possible to avoid the ratings being influenced by a single measure, the TEP did support rethinking the measures included. Overall, the TEP supported measures from the current Healthcare Effectiveness Data and Information Set (HEDIS), Consumer Assessment of

Healthcare Providers and Systems (CAHPS), Health Outcomes Survey (HOS), and some of the operational measures. Suggestions included the following: adding more evidence-based, clinical outcomes measures or redesigning current measures to assess patient outcomes (such as medication adherence); considering relevance, reliability, and the small denominator for some measures; considering “gameability,” attribution issues, provider burden, and the sensitivity of measures to small changes; and considering measures focused on trust enrollees have in the plan and network issues.

After taking into consideration feedback from the TEP and from interested parties that commented on the Advance Notice of Methodological Changes for Calendar Year (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,⁷³ we are proposing to remove seven Star Ratings measures focused on operational and administrative performance, three additional measures focused on process of care, and two additional measures focused on patient experience of care. There is a balance between streamlining the measure set and continuing to include enough measures to assess performance across the range of health care quality and to avoid contracts “teaching to the test” or focusing performance improvement efforts on a limited number of measured areas. We aim to achieve this balance by proposing initially to remove measures focused on operational and administrative performance, along with some additional process and patient experience of care measures with high performance and less variability across contracts, while retaining many measures focused on clinical care, outcomes, and patient experience and continuing to see where we can add additional outcomes measures in the future.

There are various measures currently in the Part C and Part D Star Ratings measure set that focus on operational performance or on completion of required administrative processes. While these measures have been invaluable to CMS’s efforts to monitor and improve plan performance and compliance in critical operational areas, many of these measures may be better suited as measures to monitor plan performance and compliance rather than as quality measures in the Part C and Part D Star Ratings program,

⁶⁹ <https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation>.

⁷⁰ Replacing the Medicare Advantage quality bonus program—MedPAC.

⁷¹ <https://www.cms.gov/files/document/2026-advance-notice.pdf>.

⁷² https://www.rand.org/pubs/conf_proceedings/CFA3973-1.html.

⁷³ See pages 107–110 at <https://www.cms.gov/files/document/2026-announcement.pdf> for a summary of comments.

especially since ratings for many of these measures are sensitive to small changes in performance because they have smaller denominators, such that small changes in the numerator can have a large impact on the measure Star Rating. Additionally, we have seen improvement on these measures since the inception of the Part C and Part D Star Ratings program, and MA organization and Part D sponsor performance rates are consistently fairly high.

We also propose to remove three additional process measures (Diabetes Care—Eye Exam, Statin Therapy for Patients with Cardiovascular Disease, and Members Choosing to Leave the Plan) and two patient experience of care measures (Customer Service and Rating of Health Care Quality) to further streamline the Star Ratings measure set. We want to focus more on clinical care, outcomes, and patient experience of care measures where performance is not

topped out and where there is more variability in performance across contracts. This is where there is more room for improvement and measures where we see MA organization and Part D sponsors need more incentives to perform well. Additionally, when there is little variation in performance across contracts for a measure, this does not provide meaningful information to beneficiaries or their caregivers when choosing a plan. One purpose of providing quality and performance information is to highlight differences in performance across contracts that can impact the care and services provided by the plan. Reducing the number of operational and administrative measures and removing some additional process and patient experience of care measures would also increase the relative weight of the outcome measures in the summary and overall ratings.

We propose to remove the twelve measures in Table 1 beginning with the

Star Ratings year shown in the table for each measure. Following the table, we provide additional details on our rationale for proposing to remove each measure. We expect that removing these measures would result in an overall decrease in ratings since performance on many of these measures is very high; however, we also expect that the proposed removal of the Health Equity Index (HEI; also called Excellent Health Outcomes for All) reward along with keeping the historical reward factor, discussed in more detail in section V.D. of this proposed rule, would generally increase ratings. We provide the estimated combined impact of these proposed changes in section XI.C.7. of this proposed rule.

CMS is also considering removing additional measures in the future as we continue to simplify and refocus the program. Removal of any additional measures would need to be proposed and finalized through rulemaking.

TABLE 1: MEASURES PROPOSED TO BE REMOVED FROM THE STAR RATINGS

Part C or D	Measure Name	Star Ratings Year Proposed for Removal
C	Plan Makes Timely Decisions about Appeals	2029 Star Ratings
C	Reviewing Appeals Decisions	2029 Star Ratings
C	Special Needs Plan (SNP) Care Management	2029 Star Ratings
C	Call Center – Foreign Language Interpreter and TTY Availability	2028 Star Ratings
D	Call Center – Foreign Language Interpreter and TTY Availability	2028 Star Ratings
C and D	Complaints about the Health/Drug Plan	2029 Star Ratings
D	Medicare Plan Finder Price Accuracy	2029 Star Ratings
C	Diabetes Care – Eye Exam	2029 Star Ratings
C	Statin Therapy for Patients with Cardiovascular Disease	2028 Star Ratings
C and D	Members Choosing to Leave the Plan	2029 Star Ratings
C	Customer Service	2029 Star Ratings
C	Rating of Health Care Quality	2029 Star Ratings

a. Plan Makes Timely Decisions About Appeals (Part C) and Reviewing Appeals Decisions (Part C)

We propose removing the Plan Makes Timely Decisions about Appeals (Part C) and Reviewing Appeals Decisions (Part C) measures because average performance on these measures has increased from 90 to 96 percent and 88 to 95 percent from the 2015 to 2025 Star Ratings, respectively. There is also not a lot of variation across the vast majority of contracts on these measures and the measures can have small denominators for some contracts, both of which can lead to shifts in ratings as a result of small changes in the numerator. Since the appeals process is critical to monitor as it impacts access to care, CMS would continue to monitor plan performance and issue compliance actions based on appeals data as needed and would

continue to monitor access issues through the CAHPS survey measures.

b. Special Needs Plan (SNP) Care Management (Part C)

We propose removing the SNP Care Management (Part C) measure as part of our effort to increase the focus on patient experience and outcome measures. This administrative-focused process measure indicates how often a contract completed the required health risk assessment. The goal of this assessment is to then use the results to help enrollees get the care they need. CMS is ultimately interested in whether enrollees receive needed care as indicated by this assessment and not only whether the assessment is completed. We are proposing to remove this measure since the current measure does not provide any information about whether enrollees received care as indicated by their assessments. We

would move this measure to the display page.

c. Call Center—Foreign Language Interpreter and TTY Availability (Part C and Part D)

We propose removing the Call Center—Foreign Language Interpreter and TTY Availability (Part C and Part D) measures. Average performance on these measures in the 2025 Star Ratings was very high at 94 percent on the Part C measure, and 94 percent for MA–PDP contracts and 97 percent for PDP contracts on the Part D measure. Additionally, there is not a lot of variation across the vast majority of contracts on these measures, and the measures have relatively small denominators, both of which can lead to shifts in ratings as a result of small changes in the numerator. If these measures were removed, CMS would continue to monitor plan performance

and compliance, and the Star Ratings would continue to capture similar issues related to customer service through the CAHPS survey measures.

d. Complaints About the Health/Drug Plan (Part C and Part D)

We propose removing the Complaints about the Health/Drug Plan (Part C and Part D) measure. Average performance on this measure was high at 0.23 percent for MA–PD contracts and 0.04 percent for PDP contracts in the 2025 Star Ratings (lower scores are better). The volume of complaints has significantly decreased since this measure was first introduced, and there is also not a lot of variation in this measure across contracts. CMS would continue to monitor plan performance and issue compliance actions as needed, and the Star Ratings would continue to capture similar issues related to access to care and patient experience through the CAHPS survey measures.

e. Medicare Plan Finder (MPF) Price Accuracy (Part D)

We propose removing the MPF Price Accuracy (Part D) measure. Average scores on this measure were very high at 98 for MA–PD contracts and 97 for PDP contracts in the 2025 Star Ratings. Additionally, there is not a lot of variability across most contracts on this measure. If this measure were removed, CMS would continue to monitor plan performance related to drug prices posted on MPF.

f. Diabetes Care—Eye Exam (Part C)

We propose removing the Diabetes Care—Eye Exam (Part C) measure as part of our effort to streamline the Star Ratings measure set and increase the focus on patient experience and outcome measures. There are several other measures currently in the Star Ratings that focus on diabetes care, thus, covering a similar topic area as this measure. Given the importance of diabetes care, we would move this measure to the display page.

g. Statin Therapy for Patients With Cardiovascular Disease (Part C)

We propose removing the Statin Therapy for Patients with Cardiovascular Disease (Part C) measure as part of our effort to streamline the Star Ratings measure set and increase the focus on patient experience and outcome measures. There is not a lot of variation in performance across contracts on this measure, and there are other measures, such as Medication Adherence for Cholesterol (Statins), currently in the Star Ratings that cover a similar topic area as this measure. As

noted in the Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, the National Committee for Quality Assurance (NCQA) reevaluated the Statin Therapy for Patients with Cardiovascular Disease (Part C) measure for the 2026 measurement year. The changes finalized by NCQA expand the eligible population and are considered a substantive change to the measure. CMS will include the updated Statin Therapy for Patients with Cardiovascular Disease on the 2028 display page and monitor changes in performance for this measure since statin therapy is important in lowering cholesterol and reducing the risk of cardiovascular disease.

h. Members Choosing To Leave the Plan (Part C and Part D)

We propose removing the Members Choosing to Leave the Plan (Part C and Part D) measure as part of our effort to streamline the Star Ratings measure set and increase the focus on patient experience and outcome measures. We are proposing to remove the measure based on previous feedback from Part C and D sponsors that they would prefer this measure be at the parent organization level versus the contract level or that they would like additional exclusions for the measure such as exclusions for terminations of provider networks. Additionally, without knowing the reasons for disenrollment, it is hard for enrollees to interpret what this measure score means and make meaningful comparisons between contracts. The current measure at the contract level would move to the display page.

i. Customer Service and Rating of Health Care Quality (Part C)

We propose removing the Customer Service and Rating of Health Care Quality (Part C) measures as part of our effort to streamline the Star Ratings measure set. Compared to other patient experience of care measures, there is less variation in performance across contracts on these measures. We would continue to collect these data for quality improvement purposes and report the measures on the display page.

We welcome feedback on all the potential measure removals discussed in this proposed rule, including feedback on the timing of measure removals.

2. Adding Measure

a. Depression Screening and Follow-Up (Part C)

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on

improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. (83 FR 16533). For example, we regularly review measures developed by NCQA and the Pharmacy Quality Alliance (PQA). As we continue to align with the Universal Foundation, we also propose to add the Part C Depression Screening and Follow-Up (DSF) measure to the 2029 Star Ratings (measurement year 2027). CMS will begin reporting the DSF measure on the display page for the 2026 Star Ratings. As provided at §§ 422.164(c)(3) and (4) and 423.184(c)(3) and (4), as new performance measures are developed and adopted they are initially posted on the display page for at least 2 years.

We solicited feedback regarding whether to add the DSF measure to the 2026 Star Ratings display page (using data from the 2024 measurement year) in the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and noted that it would need to go through rulemaking to be added to the Star Ratings.⁷⁴ DSF measures the percentage of eligible MA plan members who were screened for clinical depression using a standardized instrument and, if screened positive, received follow-up care within 30 days. This aligns with the U.S. Preventive Services Task Force recommendations regarding screening and follow-up for depression,⁷⁵ supports CMS's efforts to implement the Universal Foundation set of measures across quality programs, and focuses on improving the well-being of beneficiaries as well as MAHA priorities by encouraging MA health plans to screen for depression and follow-up with appropriate care. Although this is a process measure, health outcomes can be improved by identifying individuals with depression and providing treatment. There are currently no measures specific to behavioral health care in the Part C and D Star Ratings, so adding this measure would fill an important gap.

Depression is a common mental disorder that occurs in people of all ages, and estimates of major depression were 13.1 percent in people age 12 and older and 8.7 percent in people age 60 and older during the period from

⁷⁴ See page 162 at <https://www.cms.gov/files/document/2024-announcement-pdf.pdf> for a summary of comments.

⁷⁵ <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-depression-suicide-risk-adults>.

August 2021 through August 2023.⁷⁶ Depression can exacerbate other chronic medical conditions, and it increases the risk of morbidity and mortality. There is evidence that screening tools used in primary care settings can accurately identify depressed individuals and treatment can improve depression outcomes.⁷⁷

We submitted the DSF measure through the 2024 Pre-rulemaking Review Process for review by the Measures Application Partnership, which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs, and the Measures Application Partnership provided support for this measure.⁷⁸ Consensus was not reached on this measure. The committee recommended that the Merit-based Incentive Payment System (MIPS) program consider replacing their similar measure with

this one to improve alignment across quality programs⁷⁹ and to report the screening and follow-up rates separately. The HEDIS measure differs slightly from the MIPS measure since the specification is at the health plan level and also focuses on examining follow-up actions when positive screenings occur. CMS will display separate rates for screening and follow-up on the display page and take an average of the rates for the Star Ratings measure.

3. Summary of Measure Changes for the Part C and Part D Star Ratings

Table 2 summarizes the additional measure addressed in this proposed rule, beginning with the 2029 Star Ratings. The measure description listed in this table is a high-level description. The annual Star Ratings measure specifications supporting document, the *Medicare Part C & D Star Ratings Technical Notes*, provides detailed

specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. The annual Star Ratings are produced in the fall of the prior year. For example, Star Ratings for the year 2029 are produced in the fall of 2028. If a measurement period is listed as "the calendar year 2 years prior to the Star Ratings year" and the Star Ratings year is 2029, the measurement period is referencing the January 1, 2027 to December 31, 2027 period. As noted earlier in section V.B. of this proposed rule, CMS does not codify the specific measures for the Part C and Part D Quality Rating System in regulation; doing so would be unnecessarily lengthy and cumbersome due to the relative regularity with which measure specifications are updated.

TABLE 2: SUMMARY OF NEW INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2027

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Depression Screening and Follow-Up	The average percentage of eligible MA plan members who were screened for clinical depression using a standardized instrument and, if screened positive, received follow-up care within 30 days.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	Not available	Clustering	MA-PD and MA-only

C. Streamlining the Methodology, Further Incentivizing Quality Improvement, and Suggestions for New Measures

Finally, we are also soliciting feedback on ways to streamline and modify the Star Ratings methodology to further incentivize quality improvement and suggestions for new outcomes measures to promote prevention and wellness of health and drug plan enrollees to make the Star Ratings program more aligned with MAHA efforts related to healthy aging, such as nutrition and patient well-being. We are

also soliciting feedback on additional measures that could be removed in future years.

D. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

In the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120) ("April 2023 final rule"), we finalized the

addition of the Health Equity Index (HEI) reward (also called the Excellent Health Outcomes for All (EHO4all) reward)⁸⁰ along with the removal of the historical reward factor at the same time. The HEI reward was intended to further incentivize Part C and Part D contracts to focus on improving care for enrollees that are dually eligible, receive a low-income subsidy, or are disabled because these groups are at risk for poor health outcomes and Star Ratings data show gaps in the quality of care for these enrollees. This reward was finalized at 42 CFR 422.166(f)(3) and 423.186(f)(3) to be implemented

⁷⁶ <https://www.cdc.gov/nchs/data/databriefs/db527.pdf>.
⁷⁷ <https://pmc.ncbi.nlm.nih.gov/articles/PMC7661597/> and [https://www.amjmed.com/article/S0002-9343\(22\)00524-1/fulltext](https://www.amjmed.com/article/S0002-9343(22)00524-1/fulltext).
⁷⁸ <https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf>.
⁷⁹ The MIPS measure differs from the NCQA one in that the MIPS version requires a qualifying

encounter, whereas the NCQA-stewarded version looks for a screen at any time in the measurement period; the follow-up component of the MIPS version entails documentation of a follow-up plan, whereas the NCQA-stewarded version is more intensive requiring follow-up care; the follow-up timeframe in the MIPS version is on or up to 2 days after the date of the qualifying encounter, whereas the NCQA-stewarded measure uses a timeframe of on or up to 30 days after the date of the positive

screen; and the MIPS version only excludes individuals with a diagnosis of bipolar disorder, whereas the NCQA version excludes individuals with bipolar disorder or a current diagnosis of depression.
⁸⁰ In the 2026 Rate Announcement, we began to rebrand the Health Equity Index reward with a new name, the EHO4all reward. <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents/2026>.

beginning with the 2027 Star Ratings using data from the 2024 and 2025 measurement years. The historical reward factor, which incentivizes consistent high performance across Star Ratings measures, was finalized at §§ 422.166(f)(1) and 423.186(f)(1) to be removed from the Star Ratings methodology with the implementation of the HEI reward in the 2027 Star Ratings using data from the 2025 measurement year. The historical reward factor was included in the Star Ratings beginning with the 2009 Star Ratings with the purpose of adding incentives for contracts to achieve high and stable relative performance across all measures.

Since the April 2023 final rule, we have reviewed the HEI reward consistent with the Executive Order 14192, “Unleashing Prosperity Through Deregulation” and propose to remove the HEI reward from the Star Ratings methodology. We propose not to implement the HEI reward with the 2027 Star Ratings and instead continue the historical reward factor. Rather than incentivizing improvement among certain populations like those included in the HEI, CMS would instead incentivize improvement efforts on clinical care, outcomes, and patient experience, in line with the proposal in section V.B. of this proposed rule to refocus the Star Ratings measure set. We recognize that some health plans may have already expended resources on performance improvement focused on the populations included in the HEI reward; however, any improvements in performance among these populations will still contribute to higher performance on the Star Ratings by increasing measure-level scores even without the implementation of the HEI reward. Higher measure-level scores benefit health plans by improving overall performance on the Star Ratings.

This shift is part of a broader effort to refocus the Star Ratings on clinical care, outcomes, and patient experience. In section V.B. of this proposed rule, we provide more detail about the efforts to refocus the measurement set. Improvements in clinical care can lead to better patient outcomes and, ultimately, higher Star Ratings.

This shift also aligns with our focus on exploring ways to simplify and modify the Star Ratings methodology to further drive quality improvement. Rather than implement the change to the methodology to add the HEI reward and remove the historical reward factor, we instead propose to keep the methodology consistent for now as we explore ways to simplify the methodology in the future. See section

V.C. where we solicit comments on ways to simplify and modify the Star Ratings methodology to further drive quality improvement. Any such simplifications or modifications would be proposed in future rulemaking.

Typically, CMS has proposed and finalized changes to the Star Ratings methodology in advance of the measurement year (which aligns with the rules for measure updates). However, this proposal would avoid the need for updates to the Star Ratings methodology, including a significant amount of programming, as well as updates to the Star Ratings technical documentation and data display in the Health Plan Management System (HPMS), to reflect the temporary addition of the HEI reward and removal of the historical reward factor. Therefore, we do not propose to implement the HEI reward and to continue to implement the historical reward factor beginning with the 2027 Star Ratings. To remove the HEI reward and revert to the historical reward factor in the Star Ratings methodology, we propose to remove the paragraphs at §§ 422.166(f)(3) and 423.186(f)(3), and to modify §§ 422.166(f)(1) and 423.186(f)(1) to remove “Through the 2026 Star Ratings.”

E. Plan Preview of Star Ratings (§§ 422.166(h)(2) and 423.186(h)(2))

We are proposing to add additional information about the data available to MA organizations and Part D sponsors during the plan preview periods before each Star Ratings release described at §§ 422.166(h)(2) and 423.186(h)(2). During the first plan preview, CMS expects Part C and D sponsors to closely review the methodology and their posted numeric data for each measure in HPMS prior to display on MPF. The second plan preview provides an opportunity for Part C and D sponsors to review any updates from the first plan preview and preliminary Star Ratings for each measure, domain, summary rating, and overall rating. When the Star Ratings methodology was first codified in the April 2018 final rule, we anticipated that the plan preview periods would continue to evolve and it was not necessary to codify the specific display content. As the plan previews have continued to evolve, CMS has added de-identified contract-level sample data for one of each type of measure needed for MA organizations and Part D sponsors to replicate the calculation of the measure-level cut points (that is, one CAHPS measure, one measure for Part C and one for Part D that use clustering, and any measures requiring a different type

of calculation such as Complaints about the Plan). These data allow MA organizations and Part D sponsors to validate CMS’s cut point calculations. The same cut point programming is used for all other measures as the sample measures, so de-identified contract-level data for only the sample measures are displayed in HPMS during the second plan preview. We are proposing to codify our current practice of providing sample data for one of each type of measure during the second plan preview described at §§ 422.166(h)(2) and 423.186(h)(2).

F. Impact of Proposed Changes

Simulations of the impact of removing the HEI reward, keeping the historical reward factor, and removing the 12 measures as proposed in section V.B. of this proposed rule, using data from the 2025 Star Ratings (2022 and 2023 measurement years) but updating the measure set and measure weights for changes consistent with the 2026 Star Ratings (for example, reducing the weight of patient experience/complaints and access measures from 4 to 2) show most contracts (62 percent) would have no change in the overall rating. The overall rating would increase by a half star for 13 percent of contracts, would decrease by a half star for 25 percent of contracts, and would decrease by one star for one contract. Five percent of contracts would gain QBPs, and four percent of contracts would lose QBPs.

As described in this proposed rule, we are proposing adding and removing certain Star Ratings measures. The proposed new measure entails moving an existing measure from the display page to Star Ratings, which would have no impact on plan burden. The measures proposed for removal are either calculated from administrative data⁸¹ or would still be submitted by plan sponsors and, as such, there would be no decrease in plan burden. The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS’s Star Ratings related PRA packages, including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–1028 for HEDIS (CMS–10219), and OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261). Since the provisions would not impose any new or revised information collection requirements or burden, we

⁸¹ The following measures proposed for removal are calculated from administrative data: Plan Makes Timely Decisions about Appeals, Reviewing Appeals Decisions, Complaints about the Health/Drug Plan, Medicare Plan Finder Price Accuracy, Members Choosing to Leave the Plan.

are not making changes under any of the aforementioned control numbers.

We welcome feedback on these proposed changes.

VI. Improvements for Special Needs Plans

A. Model of Care (MOC) Off-Cycle Submission Window (42 CFR 422.101)

Congress first authorized special needs plans (SNP) through the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). The law authorized CMS to contract with Medicare Advantage (MA) coordinated care plans that are specifically designed to provide targeted care to individuals with special needs. Section 1859(f)(5)(A) of the Act, as added by section 164 of the Medicare Improvements for Patients and Providers Act (Pub. L. 110–275), imposes specific care management requirements for all SNPs effective January 1, 2010. As a result, all SNPs are required to implement care management requirements which have two explicit components: a National Committee for Quality Assurance (NCQA) approved, evidence-based model of care (MOC) and a series of care management services.⁸²

All SNPs must submit their MOCs to CMS for NCQA evaluation and approval and an MA organization sponsoring multiple SNPs must develop a separate MOC to meet the needs of the targeted population for each SNP type it offers as required at §§ 422.4(a)(1)(iv), 422.101(f)(3)(i), and 422.152(g). The NCQA MOC evaluation and approval process scores each of the clinical and non-clinical elements of the MOC. The Institutional Special Needs Plan (I–SNPs) and Dual-Eligible Special Needs Plan (D–SNPs) MOCs that receive a passing score from NCQA are then approved for one-, two-, or three-year periods as set forth at § 422.101(f)(3)(iii). A Chronic Condition Special Needs Plan (C–SNP) MOC that receives a passing score is approved for one year as required by section 1859(f)(5)(B)(iv) of the Act. As the MOC approval periods end, SNPs submit new MOCs to CMS for NCQA evaluation and approval during an annual renewal MOC submission window. This ensures that all operating SNPs have a current, NCQA approved, MOC in place.

CMS has acknowledged in the past that to more effectively address the specific needs of its enrollees, a SNP may need to modify its processes and

strategies for providing care during its approved MOC timeframe. A SNP that seeks to revise a MOC before the end of the MOC approval period may do so between June 1st and November 30th of each calendar year via the “off-cycle MOC submission process” outlined at § 422.101(f)(3)(iv). A D–SNP or I–SNP that decides to make revisions to their existing approved MOC may submit a summary of their off-cycle MOC changes, along with the red-lined MOC, in the Health Plan Management System (HPMS) Model of Care module for NCQA review and approval. The off-cycle submission requirements apply to substantial changes in policies or procedures as described at § 422.101(f)(3)(iv)(B)(1) and other revisions identified at § 422.101(f)(3)(iv)(B)(2) to (5). These types of MOC changes are at the discretion of the applicable MA organization offering the SNP and it is the responsibility of the MA organization to notify CMS of revisions and electronically submit their summary of changes to their MOC in HPMS for review and approval.

Since the beginning of the MOC approval process, CMS has developed, issued, and updated guidance on the MOC to support plan performance and assist in improved health outcomes. CMS had previously required initial and renewal MOCs to be submitted mid-February of the preceding plan contract year, aligning with the MA application deadline. However, as announced in an HPMS email titled “Contract Year 2027 Model of Care Submission Timeline Updates” on September 3, 2025, CMS has moved the initial and renewal MOC submission deadline to the Friday before the first Monday of June, starting with the contract year (CY) 2027 MOC submission period. The new MOC submission deadline and subsequent NCQA evaluation overlap with the current off-cycle MOC submission window. To accommodate the CY 2027 MOC submission deadline change and ensuing operational considerations both for NCQA and CMS’s HPMS, a new timeline for the off-cycle submission process is needed. As such, CMS is proposing that for CY 2027 and subsequent years, D–SNPs and I–SNPs seeking to revise their NCQA-approved MOC during the MOC approval period must submit updates and corrections between January 1st and March 31st and October 1st and December 31st of each calendar year. This would functionally provide SNPs with two separate windows of opportunity to submit off-cycle MOC changes each year. Of note, SNPs currently have a six-month

window to update or correct their MOCs; this new proposed timeline would split that period to accommodate the operational needs of CMS and NCQA as staff review initial and annual MOC submissions. CMS seeks comment on these proposed technical changes to the timeline and opportunities for improving the off-cycle MOC process for potential future rulemaking.

CMS believes there would be no change in the estimated burden from this changed timeline for SNPs submitting off-cycle MOC changes. Additionally, there would be no expected collection of information that would be new for this rule, only maintenance of past expectations around the off-cycle MOC process.

B. Passive Enrollment by CMS (§ 422.60)

Individuals who are dually eligible for both Medicare and Medicaid typically face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in unnecessary, duplicative, or missed services. One method for overcoming this challenge is through integrated care, which provides dually eligible individuals with the full array of Medicaid and Medicare benefits for which they are eligible through a single delivery system, thereby improving quality of care, beneficiary satisfaction, care coordination, and reducing administrative burden.

Integrated care options are increasingly available for dually eligible individuals, which include a variety of integrated D–SNPs. Integrated D–SNPs can provide greater integration of Medicare and Medicaid services and experiences than enrollees would otherwise receive in other MA plans or Original Medicare, particularly when an individual is enrolled in both a D–SNP and Medicaid managed care organization (MCO) offered by the same organization. When referring to integrated D–SNPs, we are referring to: applicable integrated plans (AIPs), which include fully integrated dual eligible special needs plans (FIDE SNPs), many highly integrated dual eligible special needs plans (HIDE SNPs), and a small subset of coordination-only D–SNPs. These D–SNP types meet higher standards of integration, quality, and performance benchmarks, and for AIPs, exclusively aligned enrollment (when enrollment in a parent organization’s D–SNP is limited to individuals with aligned enrollment), which we believe is a critical part of improving experiences and outcomes

⁸² For more discussion of the history of SNPs, please see Chapter 16B of the Medicare Managed Care Manual (MMCM).

for dually eligible individuals. These D-SNP types more meaningfully integrate Medicare and Medicaid services and administrative processes (such as unified appeals and grievances) than coordination-only D-SNPs that are not also AIPs.

While enrollment in integrated care options continues to grow, there are instances in which enrollees may face disruptions in coverage in integrated care plans. These disruptions can result from numerous factors, including market forces that impact the availability of integrated D-SNPs and State re-procurements of affiliated Medicaid MCOs. Such disruptions can result in enrollees being enrolled with two separate health plan organizations for their Medicaid and Medicare benefits, thereby losing the benefits of integration achieved when the same health plan organization offers both benefit packages. In an effort to protect the continuity of integrated care for dually eligible individuals, in the April 2018 final rule (83 FR 16502), we finalized a limited expansion of our regulatory authority to initiate passive enrollment for certain dually eligible individuals in instances where integrated care coverage would otherwise be disrupted.

Section 1851(c)(1) of the Act authorizes us to develop mechanisms for enrollees to elect MA enrollment, and in the April 2018 final rule (83 FR 16502), we amended the regulation at § 422.60(g) by adding § 422.60(g)(1)(iii) and (g)(2) to allow passive enrollment for full-benefit dually eligible enrollees from a non-renewing integrated D-SNP into another comparable plan. A beneficiary who is offered a passive enrollment is deemed to have elected enrollment in the designated plan if he or she does not elect to receive Medicare coverage in another way.

In the April 2018 final rule, we finalized language authorizing CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D-SNP into another integrated D-SNP, after consulting with the State Medicaid agency that contracts with the D-SNP, when CMS determines that the passive enrollment will promote continuity of care and integrated care under § 422.60(g)(1)(iii). We also finalized, under § 422.60(g)(2), requirements an MA plan would have to meet to qualify to receive passive enrollments under paragraph (g)(1)(iii). However, in multiple situations where we have attempted to implement these requirements, we have encountered difficulty with receiving integrated D-SNPs meeting the requirement in § 422.60(g)(2)(ii) that they have provider

networks and facility networks that are substantially similar to those of the relinquishing integrated D-SNP. In our attempts to utilize passive enrollment, we found that while prospective receiving integrated D-SNPs had Medicare provider and facility networks that meet the MA network adequacy criteria at § 422.116, these networks weren't substantially similar to the provider and facility networks in the relinquishing integrated D-SNPs.

We acknowledge that the substantially similar provider and facility networks requirement that is used to assess receiving integrated D-SNPs is undefined in regulation. On August 1, 2018, we published a Health Plan Management System (HPMS) memo that provided further technical guidance on how we would assess for substantially similar networks.⁸³ In this memo, we noted that, using National Provider Identifier (NPI) numbers, we would compare the MA network of the relinquishing integrated D-SNP to that of a receiving integrated D-SNP to assess overlap in provider and facility specialty types across an array of provider specialty types with the highest utilization by dually eligible individuals, which were outlined in the same HPMS memo. However, even with the additional operational guidance, a network comparison between the relinquishing and receiving plans did not result in networks that we could consider substantially similar. As such, we have not been able to implement passive enrollment as outlined in § 422.60(g).

We continue to find value in the concept of allowing passive enrollment for full-benefit dually eligible enrollees from a non-renewing or terminating integrated D-SNP to another comparable integrated D-SNP, and we continue to hear from States interested in using this provision. In order to operationalize this function, we are proposing to amend § 422.60(g)(2)(ii) to remove the requirement that the receiving integrated D-SNPs have substantially similar networks to the relinquishing integrated D-SNPs and, instead, require receiving integrated D-SNPs to provide continuity of care for all incoming enrollees for a minimum of 120 days. Specifically, we are proposing to replace the current language in § 422.60(g)(2)(ii) with the requirement

that a receiving integrated D-SNP provide continuity of care for all incoming enrollees that complies with § 422.112(b)(8)(i)(B), except that the minimum transition period would be 120 days. We note that this proposed requirement would not affect a receiving integrated D-SNP's requirement to meet network adequacy standards per § 422.116, potential compliance actions that may result from a failure to meet those requirements. We are also proposing to amend § 422.60(g)(2)(vi) to specify that an integrated D-SNP receiving passive enrollment must have the care coordinator staffing capacity to receive dually eligible enrollees through passive enrollment. We expect this coordinator staffing capacity to be sufficient to conduct required enrollee onboarding activities such as health risk assessments and care plans and meet ongoing D-SNP care coordination requirements, including those outlined at § 422.107(c). Lastly, in an effort to use consistent and accurate language throughout our processes and documentation, we are proposing to amend § 422.60(g)(2)(i) to instead describe the MA plans that can receive passive enrollment as plans that operate as an applicable integrated plan (AIP) as described at § 422.561.

We are proposing to amend § 422.60(g)(2)(ii) to require that the plan receiving passive enrollment provide continuity of care to all incoming enrollees for 120 days because we believe that this length of time for continuity of care would address the issue that we attempted to address at 83 FR 16504 in the April 2018 final rule, namely that the provider network comparability analysis would minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment and encourage retention following enrollees' transition to a new integrated D-SNP, while creating an approach that can be more feasibly implemented than the current substantially similar network requirement.

We are specifically tying the proposed amendment in § 422.60(g)(2)(ii) to § 422.112(b)(8)(i)(B) because in keeping with the spirit of the passive enrollment regulation, as discussed in the April 2018 final rule, the goal of passive enrollment is continuity of care. In the final rule titled "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," which appeared in the **Federal Register** on April 12, 2023, we finalized

⁸³ CMS, HPMS memorandum titled "Guidance on the Process for Implementing Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dual Eligible Beneficiaries", August 2018. Retrieved from: <https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2018-week1-aug-1-3>.

the provision at § 422.112(b)(8)(i)(B) requiring that, with respect to basic benefits, coordinated care plans are required to provide a minimum 90-day transition period when an enrollee currently undergoing treatment switches to a new MA plan, during which time the new MA plan may not disrupt or require reauthorization for the active course of treatment (88 FR 22205). We explain this requirement in the corresponding notice of proposed rulemaking, titled “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,” which appeared in the **Federal Register** on December 27, 2022, by stating the following: “The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days. This means that for a minimum of 90 days, when an enrollee switches to a new MA coordinated care plan, any active course of treatment must not be subject to any prior authorization requirements. During the initial 90 days of an enrollee’s enrollment with an MA coordinated care plan, the MA coordinated care plan cannot subject any active course of treatment (as defined at the proposed § 422.112(b)(8)(ii)(B)) to additional prior authorization requirements, even if the service is furnished by an out-of-network provider. We expect any active course of treatment to be documented in the enrollee’s medical records so that the enrollee, provider, and MA plan can track an active course of treatment and avoid disputes over the scope of this proposed new requirement. We also intend that an active course of treatment can include scheduled procedures regardless of whether there are specific visits or activities leading up to the procedure. To further illustrate, if an enrollee has a procedure or surgery planned for January 31st at the time of enrollment in a new MA coordinated care plan effective January 1, the new MA coordinated care plan must cover this procedure without subjecting the procedure to prior authorization. The planned surgery is a part of an active course of treatment and thus cannot be subjected to prior authorization by the MA coordinated care plan in which the

beneficiary has newly enrolled.” (87 FR 79504)

We believe that the requirements captured in § 422.112(b)(8)(i)(B) are consistent with the intention behind passive enrollment at § 422.60(g), and as such, we are proposing to apply the requirements at § 422.112(b)(8) to § 422.60(g)(2)(ii), except that continuity of care would be applicable for 120 days as opposed to 90 days, as is currently required at § 422.112(b)(8). This proposal is an attempt to balance the current 90 day requirement applicable to all coordinated care plans with the intention behind the current regulation at § 422.60(g) to minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment.

Additionally, we would like to note that in our proposed revision of § 422.60(g)(2)(ii), we are also proposing to remove the language that requires the receiving plan to have substantially similar Medicare- and Medicaid-covered benefits as the relinquishing integrated D-SNP. In the final rule titled “Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,” which appeared in the **Federal Register** on April 16, 2019 (hereafter referred to as the April 2019 final rule; 84 FR 15710), we finalized a series of provisions codifying specific integration requirements for D-SNPs pursuant to the requirements in the Bipartisan Budget Act of 2018. Since integration levels are defined both in statute and in regulation at §§ 422.2 and 422.107(d), and Medicare Part A, B, and D benefits and Medicaid benefits do not tend to differ across D-SNPs with the same integration level within a State, we do not believe that a specific assessment for substantially similar coverage of Medicare and Medicaid covered benefits is required. In such a situation where passive enrollment is implemented, we believe that an assessment of level of integration between the relinquishing and receiving integrated D-SNPs would suffice.

Our continued goal with passive enrollment is to ensure that the integrated D-SNPs receiving passive enrollments provide high-quality care, coverage and administration of benefits. Passive enrollments benefit a plan by providing an enrollee and associated payments without the plan having to successfully market to the enrollee. Thus, we continue to believe that it is important that these enrollments are

limited to plans that have demonstrated commitment to quality and are able to provide longer continuity of care to minimize service disruption for receiving dually eligible enrollees, who have complex and unique care needs. We are not proposing any other changes to § 422.60(g) or the process; receiving plans would still be held to all other standards set forth at § 422.60(g)(2). Similarly, we are not proposing changes to the current regulation at § 422.60(g)(4) regarding beneficiary notification requirements. Further, passively enrolled enrollees would still have the opportunity to opt out of the receiving plan, and § 422.60(g)(5), which describes an enrollee’s access to the special election period at § 423.38(c)(10), would still be in effect.

We welcome comments on the changes we propose at § 422.60(g)(2)(i) and (ii). Similarly, we solicit comment on our proposed revision to § 422.60(g)(2)(vi) which would require that an integrated D-SNP receiving passive enrollment have the care coordinator staffing capacity to receive dually eligible enrollees through passive enrollment. Our proposal does not define a minimum staffing capacity threshold in order to give integrated D-SNPs flexibility in implementing this proposed change. We invite comment on the feasibility of this proposed requirement, and request suggestions for potential refinement.

C. Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D-SNP and Medicaid Fee-for-Service (§§ 422.107 and 422.514)

The Contract Year 2025 Medicare Advantage and Part D final rule, which appeared in the **Federal Register** on April 23, 2024 (hereafter referred to as the April 2024 final rule; 89 FR 30448), included several provisions to simplify options for dually eligible individuals and promote greater alignment of D-SNPs and Medicaid MCOs. We explained at 89 FR 30675 that, despite progress, there remain a significant number of enrollees who receive Medicare services through one managed care entity and Medicaid services through a different entity (misaligned enrollment), rather than from one organization delivering both Medicare and Medicaid services (aligned enrollment). As expressed in the April 2019 final rule (84 FR 15699 through 15730), we continue to believe that aligned enrollment, and especially exclusively aligned enrollment, is a critical part of improving the experiences and outcomes of dually eligible individuals.

In the April 2024 final rule, we finalized a package of provisions at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h) that require that, beginning in contract year 2027, where an MA organization offers a D-SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service areas (even if there is only partial overlap of the service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dual eligible individuals, except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D-SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO. Per § 422.514(h)(2), beginning in contract year 2030, such D-SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO, except that such D-SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d). To minimize enrollment disruption associated with achieving compliance, in the April 2024 final rule, we finalized a provision at § 422.530(c)(4)(iii) that would provide a new crosswalk exception to allow one or more MA organizations that share a parent organization and offer D-SNPs subject to the new limits to crosswalk enrollees (within the same parent organization and among consistent plan types) when the MA organization chooses to non-renew or consolidate its current D-SNPs to comply with the new rules at §§ 422.504(a)(20) and 422.51(h).

In addition, in the April 2024 final rule, we codified at § 422.514(h)(3) two exceptions to the requirements at § 422.514(h)(1) and (2) for exceptions related to instances where (a) the State Medicaid agency contract (SMAC) with the MA organization differentiates enrollment into D-SNPs by age group or to align enrollment in the D-SNP with the eligibility or benefit design used in the State's Medicaid managed care program and (b) the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D-SNPs and PPO D-SNPs. To promote integrated care through aligned Medicare and Medicaid products, at § 422.514(h)(3)(ii) we finalized that the MA organization, its parent organization, or another MA

organization that shares a parent organization with the MA organization may only accept new enrollment in one D-SNP for full-benefit dually eligible individuals in the same service area as an affiliated Medicaid MCO, and such new enrollment is limited to the full-benefit dually eligible individuals who are enrolled (or are enrolling) in the Medicaid MCO.

As articulated in the April 2024 final rule (89 FR 30680), overall these changes would have several benefits. These include boosting the percentage of D-SNP enrollees in aligned enrollment, and—over time—exclusively aligned enrollment, increasing access to the comprehensive coordination of care, unified appeal processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials that come with enrollment in one or more of the various types of integrated D-SNPs; prompting MA organizations to consolidate PBPs down to a single PBP for full-benefit dually eligible individuals that is aligned with their Medicaid MCO that fully or partially overlaps with the D-SNP service area; removing some incentives for agents and brokers to target dually eligible individuals; lessening assistance needed from advocates and SHIP counselors to correct enrollment issues; and simplifying provider billing and lower the risk of inappropriate billing. For a more detailed discussion of the provisions finalized at § 422.514(h), we direct readers to the proposed rule titled “Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,” which appeared in the **Federal Register** November 15 2023, (hereafter referred to as the November 2023 proposed rule; 89 FR 78566 through 78575) and the April 2024 final rule (89 FR 30675 through 30681).

In response to our proposals in the November 2023 proposed rule, a number of commenters suggested that the enrollment limitations could create barriers to care for dually eligible individuals in States where they are not required to be in or are explicitly carved out from Medicaid managed care. (89 FR 30689 through 30690) For example, in New York, only dually eligible individuals with significant long-term care needs are required to enroll in Medicaid managed care, with the majority of dually eligible individuals

remaining in Medicaid fee-for-service (FFS). These commenters noted that D-SNPs that also contract with States as Medicaid MCOs can currently enroll individuals into their D-SNP that are enrolled in Medicaid FFS but, under the requirements finalized in the April 2024 final rule, those D-SNPs would not be able to enroll these individuals beginning in 2027 and would be required to disenroll them as of 2030. Commenters indicated that these individuals are better served in D-SNPs where they receive coordination of their Medicare and Medicaid FFS services. The commenters offered several suggestions for how CMS could address these concerns: (a) limiting the proposal to States that require mandatory enrollment for dually eligible individuals, including those who do not receive long-term care services, (b) implementing a limited exception process for States that would allow MA organizations with an affiliated Medicaid MCO to offer at least one D-SNP PBP that is not exclusively aligned and that can enroll dually eligible individuals who maintain Medicaid FFS coverage and (c) phasing in the proposal over time.

In the April 2024 final rule, we did not adopt any of these suggestions. At 89 FR 30690, we outlined potential drawbacks to limiting the § 422.514(h) provisions to only States that require mandatory Medicaid managed care enrollment for dually eligible individuals. These drawbacks included narrowing the number of States in which these policies would apply, thus reducing the extent to which we would achieve the benefits. It would also raise potential complexity in States where certain subpopulations of dually eligible individuals are mandatorily enrolled, but others are not. We further stated that allowing each MA organization with an affiliated Medicaid MCO to offer at least one D-SNP that is not exclusively aligned with its affiliated Medicaid MCO for the purpose of enrolling dually eligible individuals who are enrolled in Medicaid FFS would similarly reduce the extent to which we would achieve the benefits described in the proposed rule, create additional operational complexity for States and CMS to administer and monitor, and would likely be more complicated to explain from a beneficiary communications and messaging perspective compared to the proposal that we finalized in the April 2024 final rule. Finally, we stated our belief that the phase-in of the policy would provide ample time for transition; the finalized requirement limits new enrollment to individuals

enrolled in both a D-SNP and affiliated Medicaid MCO offered under the same parent organization starting in 2027 and then disenrolling those enrollees who do not have aligned enrollment in the D-SNP's affiliated Medicaid MCO in 2030. MA organizations would have two bid cycles and contract years (2025 and 2026) during which D-SNPs with affiliated Medicaid MCOs may prepare for the first phase of enrollment limitations.

Since we codified the package of provisions in the April 2024 final rule, we have received feedback from stakeholders on some challenges in implementing these provisions in States without mandatory Medicaid managed care for the dual eligible population. For example, given that New York does not require mandatory Medicaid managed care for its Integrated Benefits for Dually Eligible Enrollees (IB-Duals) program, participating HIDE SNPs may enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS or an unaffiliated Medicaid MCO. These HIDE SNPs do not have aligned enrollment. Without any change, in 2030, these HIDE SNPs would need to disenroll any enrollees who do not have aligned enrollment in the HIDE SNP's affiliated Medicaid MCO. In other words, beginning in 2027, these HIDE SNPs could no longer enroll any new dually eligible individuals who are enrolled in Medicaid FFS or an unaligned Medicaid MCO, and, in CY 2030, these HIDE SNPs would need to disenroll Medicaid FFS enrollees and any individuals enrolled in an unaligned Medicaid MCO.

In States that do not require mandatory Medicaid managed care for all of their full-benefit dually eligible individuals, we are also concerned about the § 422.514(h) requirements potentially disadvantaging MA organizations offering coordination-only D-SNPs and HIDE SNPs that both enroll full-benefit dually eligible individuals in the same service areas. Pennsylvania is one of these States with its Community HealthChoices program for Medicaid managed care plan for long-term services and supports. In this preamble, we will use the D-SNP landscape in Pennsylvania as an illustration of this potentially disadvantaging situation. The requirements at § 422.514(h) do not apply to MA organizations in the State that only offer coordination-only D-SNPs since these MA organizations, their parent organizations, or any entity that shares a parent organization with the MA organization do not also contract with Pennsylvania as a Medicaid MCO that enrolls full-benefit

dually eligible individuals. However, the § 422.514(h) requirements do apply to the State's HIDE SNPs. In CY 2025, several MA organizations offer HIDE SNPs and coordination-only D-SNPs in Pennsylvania that both enroll full-benefit dually eligible individuals. We note that in Pennsylvania, these HIDE SNPs do not have aligned enrollment. Per § 422.2, a HIDE SNP requires the provision of coverage of Medicaid benefits under a capitated contract between the State Medicaid agency and the MA organization; MA organization's parent organization, another entity that is owned and controlled by its parent organization; or a local nonprofit public benefit corporation. As we noted previously in this preamble, in the April 2024 final rule, we finalized a policy that, beginning in 2027, where an MA organization offers a D-SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service areas (even if there is only partial overlap of the service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dual eligible individuals, except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D-SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO.

In a State like Pennsylvania that does not mandate Medicaid managed care, those MA organizations offering a HIDE SNP with unaligned enrollment will no longer be permitted to enroll unaligned full-benefit dually eligible individuals into the HIDE SNP or allow full-benefit dually eligible individuals to enroll in the coordination-only D-SNP, unlike those MA organizations that only offer coordination-only D-SNPs in the State and do not contract with Pennsylvania as a Medicaid MCO. In 2030, MA organizations with unaligned HIDE SNPs would need to disenroll any unaligned full-benefit dually eligible individuals from their HIDE SNP. In a State like Pennsylvania that does not mandate Medicaid managed care, we believe that our regulation as-is at § 422.514(h) could create an incentive for MA organizations to terminate their HIDE SNP and transition dually eligible enrollees to the coordination-only D-SNP, which could continue to enroll full-benefit dually eligible individuals regardless of whether an enrollee receives their Medicaid coverage

through Medicaid FFS or an unaligned Medicaid managed care plan, allowing such a plan to maintain maximum enrollment. For these reasons, we believe that the application of § 422.514(h) to the MA organizations with unaligned HIDE SNPs and coordination-only D-SNPs puts them at a disadvantage in comparison to those MA organizations with only coordination-only D-SNPs, since full-benefit dually eligible individuals are able to, and do, remain in Medicaid FFS in States without mandatory Medicaid managed care. This is an unintended consequence of § 422.514(h), inconsistent with our goals to promote integrated care. While our goal is to have full-benefit dually eligible individuals enrolled in integrated D-SNPs, we do not want to inadvertently prevent integrated D-SNPs from continuing to enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS. We believe MA organizations offering integrated D-SNPs in other States with voluntary Medicaid managed care for the dually eligible population, such as Michigan and the District of Columbia, may face similar challenges.

We are proposing to amend §§ 422.107(d)(1) and 422.514(h) to allow D-SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D-SNP to continue enrollment of full-benefit dually eligible individuals in a D-SNP in the same service area where those individuals are enrolled in Medicaid FFS. These proposed changes would address the challenges of MA organizations complying with the requirements at § 422.514(h) in States where there is no mandatory Medicaid managed care program and avoid the need for MA organizations in those States to cease enrolling full-benefit dually eligible individuals who are in Medicaid FFS starting in 2027 and disenroll those members in 2030 as currently required under § 422.514(h).

We propose to amend SMAC requirements at § 422.107(d)(1) through adding a new paragraph (i). For any SMACs that allow coordination-only D-SNPs (as established under § 422.107(d)(1)) to enroll full-benefit dually eligible individuals, the newly proposed paragraph (i) would require the SMAC to stipulate that such full-benefit dually eligible beneficiaries cannot be enrolled in a Medicaid MCO that is owned and controlled by an entity other than the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization. In other words, the proposed amendment to § 422.107(d)(1)

would permit coordination-only D-SNPs that enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS.

At § 422.514(h)(3), we propose to add new paragraphs (iii) and (iv). For any SMACs that permit full-benefit dually eligible individuals to enroll in (a) a coordination-only D-SNP per proposed amendment at § 422.107(d)(1)(i) or (b) a HIDE SNP with a majority of individuals enrolled in Medicaid FFS, the new paragraph proposed at § 422.514(h)(3)(iii) would allow the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization to offer one or more additional D-SNPs for full-benefit dually eligible individuals in the same service area. Limiting the proposed exception at § 422.514(h)(3) to HIDE SNPs with a majority of enrollees in Medicaid FFS would prevent application of this exception to HIDE SNPs with a minority of Medicaid FFS enrollees and a majority of Medicaid managed care enrollees whose Medicaid MCO is unaligned with the HIDE SNP. HIDE SNPs with a majority of enrollees in unaligned Medicaid MCOs would have less incentive to achieve aligned membership and detract from the intended goals of § 422.514(h). We propose adding a new paragraph (iv) at § 422.514(h)(3) that would require MA organizations with D-SNPs subject to § 422.514(h)(3)(iii) to comply with care coordination responsibilities at § 422.562(a)(5). Per § 422.562(a)(5)(i), D-SNPs must offer to assist an enrollee in that D-SNP with obtaining Medicaid-covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid FFS or a Medicaid managed care plan, such as a Medicaid MCO, prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) as defined in § 438.2. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance are outlined at § 422.562(a)(5)(i)(A). We are considering amending § 422.562(a)(5)(i)(A) to require MA organizations with D-SNPs subject to proposed § 422.514(h)(3)(iii) to report to CMS on the proactive outreach they provide to Medicaid FFS enrollees, the type of assistance they offered to these enrollees, and whether these enrollees received the relevant Medicaid services. We are not proposing

to require MA organizations with D-SNPs subject to proposed § 422.514(h)(3)(iii) to report their efforts to meet § 422.562(a)(5)(i) to CMS since such reporting would add burden for MA organizations and we may be able to leverage existing oversight mechanisms, such as models of care (MOCs), CMS program audits, monthly calls between MA organizations and CMS account managers, and existing State Medicaid FFS reporting to CMS instead of adding new plan reporting requirements. We solicit comments on whether we should amend § 422.562(a)(5)(i)(A) to require MA organizations with D-SNPs to report on their activities for assisting Medicaid FFS enrollees in obtaining Medicaid covered services instead of or in addition to the existing oversight mechanisms outlined.

Collectively, we believe these proposals at §§ 422.107(d)(1)(i) and 422.514(h)(3) would benefit MA organizations operating multiple D-SNPs that enroll full-benefit dually eligible individuals in States without mandatory Medicaid managed care. In States like New York, our proposed changes would remove the disadvantage MA organizations that offer HIDE SNPs will encounter starting (a) in 2027, when they would need to stop enrolling full-benefit dually eligible individuals into HIDE SNPs that enroll Medicaid FFS enrollees and (b) in 2030, when they would need to disenroll full-benefit dually eligible individuals from HIDE SNPs that enroll Medicaid FFS enrollees. Similarly, in States like Pennsylvania, our proposed changes would address the disadvantage MA organizations that offer HIDE SNPs and coordination-only D-SNPs will encounter starting (a) in 2027, when they would need to stop enrolling full-benefit dually eligible individuals into coordination-only D-SNPs and (b) in 2030, when they would need to disenroll full-benefit dually eligible individuals from coordination-only D-SNPs that enroll Medicaid fee-for-service enrollees. We do not believe these changes would detract from the goal of the provisions we codified in the April 2024 final rule, which was to increase the percentage of D-SNP enrollees in aligned enrollment, and—over time—exclusively aligned enrollment. When Medicaid FFS is available and HIDE SNPs can enroll individuals who are in Medicaid FFS, exclusively aligned enrollment cannot be achieved.

In the April 2024 final rule, we received comments concerning the applicability of the enrollment limitation policies at § 422.514(h) on

unique Medicaid managed care programs. Among others, commenters raised specific questions about the applicability of this rule to D-SNPs in Puerto Rico (89 FR 30697). We responded to these comments and noted that MA organizations that offer multiple D-SNPs participating in the Platino program in Puerto Rico would be required to only offer one D-SNP starting in 2027 for full-benefit dually eligible individuals in a service area where an MA organization, its parent organizations, or an entity that shares a parent organization with the MA organization also offers an affiliated Medicaid MCO unless those D-SNPs meet the exception finalized at § 422.514(h)(3).

Currently, Puerto Rico is the only U.S. Territory that offers D-SNPs. We note that the U.S. Territories, including Puerto Rico, are unique, as the Medicaid program in the U.S. Territories differs from Medicaid programs operating in the States and the District of Columbia in several notable ways. The Medicare Savings Programs, as defined at section 1144(c)(7) of the Act and 42 CFR 435.4, are Medicaid eligibility groups through which Medicaid assists low-income Medicare beneficiaries with their Part A and/or Part B premiums, and for many enrollees, cost-sharing. The MSPs are mandatory Medicaid eligibility groups for the 50 States and the District of Columbia, but optional for the U.S. Territories per section 1905(p)(4)(A) of the Act. Currently, no U.S. Territory has adopted the MSPs. Additionally, per section 1860D–14(a)(3)(F) of the Act and 42 CFR 423.907(a)(1), low-income Part D eligible individuals who reside in the U.S. Territories are ineligible for the Part D low-income subsidy, which provides cost-sharing and premium assistance to low-income Part D-eligible in the 50 States and the District of Columbia in accordance with section 1860D–14 of the Act and 42 CFR part 423 subpart P. While traditional funding sources for Medicare premiums are unavailable in the U.S. Territories, D-SNPs have the discretion to apply their MA rebate toward the Part B premium amount. (For CY 2026, we note that D-SNPs in Puerto Rico differentiate their PBPs by level of Part B premium reduction amount and supplemental benefits.) Additionally, premiums for Part D are covered by the Enhanced Allotment Plan (section 1935(e) of the Act), a specific source of funding for prescription drugs for the U.S. Territories.

Upon further consideration and given the unique landscape in the U.S. Territories, including Puerto Rico, we are proposing an exception at

§ 422.514(h)(3)(v). The proposed exception would exempt MA organizations operating in U.S. Territories that have not adopted MSP from the requirements at § 422.514(h)(1)(i) that otherwise would require—beginning in contract year 2027—the MA organization to only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals.

We acknowledge that this proposal is a change from what we previously stated in response to comments in the April 2024 final rule. We also acknowledge that upon further consideration and review, we may, in future rulemaking, reconsider this proposed exception at § 422.514(h)(3)(v). These proposed changes target MA organizations in States with voluntary Medicaid managed care enrollment and seek to level the playing field in the marketplace for impacted D–SNPs. The proposed change at § 422.514(h)(3)(v) is intended to acknowledge the uniqueness of D–SNP landscapes in the U.S. Territories.

We solicit comments on all aspects of our proposal, including whether the advantages of the proposed changes would excessively detract from the original goal of the provisions codified in the April 2024 final rule. For example, we are interested in stakeholders' perspectives on the value of non-AIP HIDE SNPs with a majority of Medicaid FFS enrollees and whether we should establish an exception for them at proposed § 422.514(h)(3)(iii) at all or limit that exception to a shorter period of time, such as 2027 through 2029. While we identified a few States that we expect would benefit from our proposals, we invite commenters to identify other States that could benefit or be negatively impacted. As outlined earlier in this section, we also solicit comments on whether we should amend § 422.562(a)(5)(i)(A) to require MA organizations with D–SNPs subject to proposed § 422.514(h)(3)(iii) to report on their activities to assist Medicaid FFS enrollees with obtaining Medicaid covered services enrollees instead of or in addition to the existing oversight mechanisms. Further, we solicit comment on the likely effectiveness of our proposed regulation in balancing the roles of D–SNPs in the U.S. Territories to fill the gaps of MSP and Part D LIS while also providing robust Medicare benefits to dually eligible individuals. We are also interested in perspectives on how limiting D–SNPs in the U.S. Territories would affect

enrollees and the consumer choice in U.S. Territories.

D. Contract Modifications for D–SNPs Following State Medicaid Agency Contract Termination (§ 422.510)

MA organizations are required to have contracts with CMS to operate each year. Section 1857(h)(2) of the Act provides authority for the Secretary to immediately terminate a contract with an MA organization in instances where the Secretary determines that a delay in termination resulting from compliance with the procedures in section 1857(h)(1) of the Act would pose an imminent and serious risk to the health of enrolled Medicare beneficiaries. In the final rule titled “Medicare Program; Establishment of the Medicare+Choice Program,” which appeared in the **Federal Register** on June 26, 1998 (hereafter referred to as the June 1998 final rule; 63 FR 35018), we finalized regulations at § 422.510 which outline processes for terminations of contracts by CMS, while providing conditions in which contracts may be found terminable. Such conditions include failure to carry out the contract, carrying out the contract in a manner that is inconsistent with the efficient and effective administration of MA regulations, and no longer being able to meet the applicable conditions put forth in MA regulations. In the decades since this rule was first finalized, we have continued to refine the conditions in which CMS may terminate an MA contract at § 422.510 and elsewhere in Part 422.

D–SNPs are MA plans that coordinate the delivery of Medicare and Medicaid services for individuals who are eligible for such services and enrolled in the plan. In addition to the standard contract an MA organization must have with CMS to operate, per section 1859(f)(3)(D) of the Act, MA organizations offering D–SNPs must also have a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for individuals entitled to Medicaid. Because D–SNPs are required to have contracts with the State Medicaid agency (SMACs), States have significant control over the availability of D–SNPs in their markets given the State's discretion in contracting with D–SNPs in combination with the State's control over its Medicaid program. We discussed this relationship between States and MA organizations in the final rule titled “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory

Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,” which appeared in the **Federal Register** on May 9, 2022, specifically at 87 FR 27763.

Because of the relationship between the State and the D–SNP, the provision and continuation of SMACs are sensitive to State policy changes and operational choices. To illustrate this, we look to Medicaid MCO procurement timelines and decisions. Some States use procurement processes to select the Medicaid MCOs that will provide Medicaid benefits to the enrollees in the State. The timeline for these procurements is distinct to each State and may operate off-cycle from MA contracting at the Federal level. Additionally, the duration of the procurement may vary based on several factors. If a State decides not to contract with a particular Medicaid MCO, which may occur off-cycle from the calendar year, such a procurement decision may require termination of a Medicaid MCO contract. Termination of the Medicaid MCO contract would trigger termination of the SMAC, if the terminating Medicaid MCO is an affiliated entity with a D–SNP that has a SMAC in effect. For example, if a State with FIDE SNPs reprocurd their Medicaid MCOs and one of the existing Medicaid MCOs lost the reprocurement, that FIDE SNP would need to terminate when the Medicaid MCO terminates.

As was noted earlier in this preamble, D–SNPs are statutorily required to have a SMAC to operate in a State. In the example given previously, if a Medicaid MCO that is an affiliated entity with a D–SNP loses a State procurement or otherwise has its Medicaid MCO contract terminated, the State also terminates the SMAC and the D–SNP cannot continue to operate. This action requires that the contract between the D–SNP and CMS be terminated. As more States move towards integrated care and contract with Medicaid MCOs through the result of procurements, we have encountered instances where a SMAC is terminated by a State during the plan year. In those instances, CMS has worked with the respective State and the MA organization whose SMAC is being terminated to mutually terminate the contract per § 422.508, a process by which CMS, the State and the D–SNP are able to agree on a timeline for termination and the provision of notice to enrollees of such termination, in an effort to create a smoother transition to an alternative plan for the plan's enrollees.

However, an MA organization with a terminating SMAC is not required to seek a mutual termination of its MA contract with CMS. Absent the cooperation of the MA organization to mutually terminate in situations where the MA organization no longer holds a SMAC with the State, we are concerned that enrollees may experience harm by losing access to their integrated care, including access to known providers and care plans, as the D-SNP in which they are enrolled is no longer able to provide benefits, or arrange for benefits to be provided, for individuals entitled to Medicaid. In these instances, CMS will need to seek immediate termination to protect beneficiaries.

At § 422.510(a)(4), we are first proposing to add a new paragraph (xvii) to establish that CMS may terminate a contract if the MA organization is no longer eligible to offer a D-SNP because the MA organization does not hold a contract with the State Medicaid agency consistent with § 422.107(b). Our goal in adding this new clause is to codify that the loss of a SMAC constitutes a valid basis for contract termination under CMS authority per section 1859(f)(3)(D) of the Act.

Secondly, at § 422.510(b)(2)(i), we are proposing to add paragraph (D) to state that the procedures specified in paragraph (b)(1), related to when CMS notifies the MA organization and when the MA organization must notify its enrollees and the general public, do not apply if the contract is being terminated based on the proposed addition of § 422.510(a)(4)(xvii). We are proposing that when a D-SNP contract is terminated because the State has terminated the affiliated contract with the Medicaid MCO or the State has terminated the SMAC, it is cause for CMS to make the MA contract termination immediate. When a State terminates the Medicaid MCO affiliated with the D-SNP or terminates the SMAC, D-SNP enrollees who are otherwise entitled to medical assistance under a State plan under title XIX of the Act would be in jeopardy of not having access to the Medicaid services to which they are entitled, given that, as required by § 422.2, D-SNPs coordinate the delivery of Medicare and Medicaid services for eligible individuals and may provide coverage of Medicaid services. It is our belief that a delay in D-SNP contract termination could disrupt access to Medicaid benefits for those who are eligible, which would pose an imminent and serious risk to the health of the organization's enrollees, rising to the standard put forth in section 1857(h)(2) of the Act and warranting immediate termination of contract by

CMS. We believe that where the MA organization does not agree to a mutual termination in coordination with the termination of the affiliated Medicaid MCO contract and/or SMAC, an immediate termination would be appropriate. However, we note that our proposed amendments to §§ 422.510(a)(4)(xvii) and (b)(2)(i)(D) do not preclude a MA organization from seeking termination of a contract by mutual consent, per § 422.508.

We note that when an MA organization has multiple plans under one contract, per § 422.503(e) CMS may sever the D-SNP from the rest of the contract, in effect allowing CMS to renew only the portion of the contract that does not include the D-SNP affiliated with the terminated SMAC.

Proposed § 422.510(b)(2)(i)(D) would codify the process of immediate termination of contract by CMS when the D-SNP does not have a SMAC. We believe that the MA organization in this situation does not need and would not benefit from an opportunity to develop and implement a corrective action plan as required at § 422.510(c)(1) given that the only way to correct the issue would be to execute a SMAC with the State. States have the ability to issue corrective action plans to the D-SNPs with whom they hold contracts. Many States, in their SMACs, include language to this effect. Additionally, as in the example given previously, if a Medicaid MCO that is an affiliated entity with a D-SNP loses a State procurement, the State also terminates the SMAC. In either of these instances, allowing D-SNPs the opportunity to develop and implement a corrective action plan per § 422.510(c)(1) would not provide the D-SNP with an avenue to correct any underlying issue that resulted in the State's termination of the SMAC. The SMAC termination, including any related opportunity to pursue a corrective action plan offered by the State, will have already occurred by the time the MA contract is terminated. Moreover, State procurement decisions operate separately from MA contracting decisions through CMS and would not be amenable to a cure or a corrective action plan as described in § 422.510(c)(1). Furthermore, any further delay in termination of the D-SNP contract poses imminent and serious risk to the health of the organization's enrollees as previously described in this preamble, rising to the standard put forth in section 1857(h)(2) of the Act. As such, we are lastly proposing that termination of a SMAC be included as an exception to the opportunity for plans to develop and

implement a corrective action plan, at § 422.510(c)(2)(iv).

We request comment on this proposal, including but not limited to whether this package of provisions will accomplish the goals we have laid out in this preamble and whether there should be any other additional modifications to consider.

E. Limitation on D-SNP-Only Contracts Submitting Materials Under the Multi-Contract Entity Process (§§ 422.2261 and 423.2261)

Sections §§ 422.2261(a) and 423.2261(a) require MA organizations and Part D sponsors to submit all marketing materials, all election forms, and certain designated communication materials for CMS review. These regulations state that the HPMS Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for CMS review. They also specify that materials must be submitted to the HPMS Marketing Module by the MA organization or Part D sponsor or, where materials have been developed by a Third Party Marketing Organization (TPMO) for multiple MA organizations or plans, by a TPMO with prior review of each MA organization on whose behalf the materials were created or will be used. In addition, §§ 422.2262(d) and 423.2262(d) describe how MA organizations and Part D sponsors must use a standardized method of identification for oversight and tracking for materials received by beneficiaries including the MA organization's contract or Multi-Contract Entity (MCE) number (such as an "H" number for MA plans or "Y" number for an MCE).

Under § 422.107(e), a State Medicaid agency may require MA organizations offering D-SNPs with exclusively aligned enrollment to do both of the following: (1) apply for, and seek CMS approval to establish and maintain, one or more MA contracts that only include one or more D-SNPs with a service area limited to the State; and (2) use required materials that integrate Medicare and Medicaid content including, at a minimum, the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory that meets Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of Title 42 of the CFR. We refer to MA contracts that only include one or more D-SNPs with a service area limited to the State as D-SNP-only contracts. If a State elects to require D-SNP-only contracts under § 422.107(e)(1), per § 422.107(e)(3)(i), CMS grants State Medicaid agency officials access to

HPMS for purposes of oversight and information sharing for these D–SNP-only contracts. For CY 2026, 13 States have D–SNP-only contracts and therefore have access to HPMS for oversight of these contracts in their State. This State oversight includes access to the HPMS Marketing Module for purposes of reviewing materials submitted by D–SNP-only contracts. These States only have access to review materials submitted under the contract number (H number) in HPMS for D–SNP-only contracts.

For material oversight, per § 438.10(c)(5), States are required to ensure, through their Medicaid managed care contracts, that each MCO, PIHP, PAHP, and primary care case management (PCCM) entity provides the information to each enrollee consistent with § 438.10(f)–(i), as applicable. In addition, per § 438.104(b), MCO, PIHP, PAHP, PCCM, or PCCM entities cannot distribute marketing materials without first obtaining State approval. The entity's contract with the State must also specify the methods by which the entity ensures that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the beneficiaries or the State Medicaid agency.

Since contracts with exclusive alignment of Medicare and Medicaid must meet the material requirements of both CMS and the State, prior to the adoption of § 422.107(e), MA organizations were required to submit materials to the State and CMS separately. However, States requiring D–SNP-only contracts have access to HPMS for reviewing these materials, and they can require the MA organizations offering D–SNP-only contracts to submit materials in the HPMS marketing module for State review. This State access decreases plan burden by allowing the D–SNP to submit the material once in HPMS for concurrent joint review by CMS and the State, as applicable, rather than having to separately submit materials to the State for review and then to CMS. This can also shorten the total review time for the MA organization and give it more time to meet tight timeframes for releasing materials to enrollees.

If an MA organization were to submit a material under an MCE number that applies to multiple contracts, the applicable State Medicaid agency would not be able to either view or review that material in the HPMS Marketing Module. States only have access to information in HPMS for the specific D–SNP-only contracts in their State. Because MCE numbers cover multiple contracts across multiple States, CMS

doesn't allow State staff to access materials submitted under an MCE number, even if an MA organization includes materials for their State. MA organizations could potentially submit a substantial number of materials in HPMS under the MCE number, including their D–SNP-only contracts, but the State would not be able to view any of them due to their submission under the MCE number. To address this challenge, CMS has programmed the HPMS marketing module so that D–SNP-only contracts cannot submit materials under an MCE number. In addition, States with D–SNP-only contracts have added language in their SMACs to prohibit submission of materials in the HPMS Marketing Module under the MA organization's MCE number. Instead, States are requiring that MA organizations with D–SNP-only contracts submit materials for review under their contract ID number.

To ensure that D–SNP-only contracts are meeting the material requirements of both Medicare and Medicaid, we believe that it is important to clarify that MA organizations with D–SNP-only contracts cannot submit materials using the MA organization's MCE number for D–SNP-only contracts, nor can TPMOs submit materials on behalf of the MA organization for D–SNP-only contracts using an MCE number. This requirement applies to all plan benefit packages within D–SNP-only contracts under § 422.107(e)(1). Since States have already been requiring this approach through their SMACs and the HPMS Marketing Module is set up to prevent D–SNP-only contracts from submitting materials under an MCE number, we do not expect this update to add burden for any MA organizations; the current process will not change.

The Medicare Communications and Marketing Guidelines (MCMG) provide additional detail on §§ 422.2261(a)(3) and 423.2261(a)(3) noting that the multi-plan submission process is intended for TPMOs that submit for multiple organizations. The MCMG states that if the third party's marketing materials only mention one MA organization, then the plans should submit the material directly to CMS using the standard submission process. Since we are prohibiting submissions under the MCE number for D–SNP-only contracts and TPMOs cannot submit materials under the contract ID number, there is no way for TPMOs to submit materials directly for D–SNP-only contracts in the HPMS Marketing Module. The MA organization must submit all materials to be used by TPMOs for D–SNP-only contracts.

Under our authority to interpret, implement, and carry out the Part C and D programs under sections 1851(h), 1851(j), 1852(c), 1860D–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(l) of the Act, we are proposing to add a requirement at §§ 422.2261(a)(3) and 423.2261(a)(3) that MA organizations offering D–SNPs with exclusively aligned enrollment subject to § 422.107(e) must submit all materials for the contract in HPMS under the MA organization's contract number. MA organizations and TPMOs may not submit materials for the contract under the organization's MCE number as described in §§ 422.2262(d)(2)(i) and 423.2262(d)(2)(i).

We welcome comment on our proposal.

F. Request for Information: C–SNP and I–SNP Growth and Dually Eligible Individuals

Please note, this is a request for information (RFI) only. In accordance with implementing regulations of the PRA, specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Per the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), chronic condition special needs plans (C–SNPs), dual eligible special needs plans (D–SNPs), and institutional special needs plans (I–SNPs) are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals. C–SNPs restrict enrollment to special needs individuals with specific severe or disabling chronic conditions as defined at § 422.2. The April 2024 final rule amended the definition of severe or disabling chronic conditions at § 422.2 by outlining the specific co-morbid and medically complex chronic conditions that qualify for C–SNP enrollment (89 FR 30661 through 30666). I–SNPs restrict enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent per § 422.2. The April 2024 final rule added three additional I–SNP subtypes: facility-based institutional

special needs plan (FI-SNP), hybrid institutional special needs plan (HI-SNP), and institutional-equivalent special needs plan (IE-SNP). (89 FR 30649 through 30653) D-SNPs are specialized MA plans for individuals who are entitled to medical assistance under a State plan under Title XIX, per § 422.2.

1. Growth in C-SNPs With High Proportion of Dually Eligible Enrollees

The number of C-SNPs offered by MA organizations has increased substantially in recent years. As outlined in Table FF1, MA organizations offered 207 C-SNPs in CY 2021 and 385 C-SNPs in CY 2025,

representing growth of 85% over that timeframe. C-SNP enrollment grew from 387,920 enrollees in CY 2021 to 1,103,194 enrollees in CY 2025, an increase of 184%. Higher levels of enrollment growth occurred between CY 2023 and CY 2024 (41.7%) and between CY 2024 and CY 2025 (67.5%).

TABLE FF1: C-SNPS AND THEIR ENROLLMENT: CY 2021 - 2025

Year	Number of C-SNPs	Total C-SNP Enrollment	Percent Annual Growth in C-SNP Enrollment	Total Dually Eligible Individual Enrollment in C-SNPs	Percent Annual Growth Total Dually Eligible Individual Enrollment in C-SNPs	Total Dually Eligible Individual Enrollment as Percent of Total C-SNP Enrollment
2021	207	387,920		103,877		26.8
2022	271	407,199	5.0	104,986	1.1	25.8
2023	306	464,837	14.2	113,765	8.4	24.5
2024	312	658,710	41.7	133,706	17.5	20.3
2025	385	1,103,194	67.5	210,983	57.8	19.1

Source: CMS analysis of Integrated Data Repository (IDR) data for January enrollment for CY 2021 – 2025.

The number of dually eligible individuals enrolled in C-SNPs also increased over the same period of time. As shown in Table FF1, the number of dually eligible individuals enrolled in C-SNPs grew from 103,877 enrollees in CY 2021 to 210,983 enrollees in CY 2025, an increase of more than 100 percent. The highest level of growth during that timeframe occurred between CY 2024 and CY 2025 with enrollment of dually eligible individuals increasing from 133,706 enrollees in CY 2024 to 210,983 enrollees in CY 2025, an increase of 57.8 percent in one year.

Over the same timeframe, the number of C-SNPs with a high proportion of dually eligible enrollees increased. Per § 422.514(d), we define D-SNP look-alikes as non-SNP MA plans with 60 percent or more dually eligible enrollment. We used this threshold to identify C-SNPs in CY 2021 through CY 2025 with a similarly high level of dually eligible enrollees. Table FF2 shows the number of C-SNPs with

dually eligible individuals representing 60 percent or more of total enrollment grew from 16 C-SNPs in CY 2021 with 59,164 dually eligible enrollees to 66 C-SNPs in CY 2025 with 104,237 dually eligible enrollees. This experience represents a 313 percent increase in the number of C-SNPs with high concentrations of dually eligible enrollees. The most substantial level of enrollment growth (63.5 percent) during this timeframe occurred from CY 2024 to CY 2025 with dually eligible enrollment increasing from 63,738 enrollees in 49 C-SNPs to 104,437 enrollees in 66 C-SNPs.

At least one C-SNP with 60 percent or more dually eligible enrollees has been offered in the following 26 States for at least one year during the CY 2021 through CY 2025 time span: Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Iowa, Indiana, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nevada, New Hampshire,

New Mexico, Ohio, Oregon, South Carolina, Tennessee, Texas, Vermont, and Virginia. For CY 2025, MA organizations offered C-SNPs with high concentrations of dually eligible individuals in 14 States, listed in order of number of such C-SNPs per State: California (31 C-SNPs); Arizona (7 C-SNPs); Illinois (6 C-SNPs); New Mexico (5 C-SNPs); Indiana, Minnesota, Nevada, Oregon (2 C-SNPs); Connecticut, Idaho, Kansas, New Hampshire, Texas, Vermont (1 C-SNP). The vast majority (85.4 percent) of the dually eligible individuals enrolled in these CY 2025 C-SNPs are full-benefit dually eligible individuals. We provide more detail on C-SNPs with a high concentration of dually eligible individuals in California, Arizona, Illinois, and New Mexico given these States have the largest number of such C-SNPs during the CY 2021 through CY 2025 timeframe.

TABLE FF2: C-SNPs WITH DUALY ELIGIBLE INDIVIDUALS REPRESENTING 60 PERCENT OR MORE OF TOTAL ENROLLMENT: CY 2021-2025

Year	Number of C-SNPs	Total C-SNP Enrollment	Total Dually Eligible Individual Enrollment in C-SNPs	Total Full-Benefit Dually Eligible Individual Enrollment in C-SNPs	Total Partial-Benefit Dually Eligible Individual Enrollment in C-SNPs	Total Full-Benefit Dually Eligible Individual Enrollment as Percent of Total Dually Eligible C-SNP Enrollment
2021	16	71,150	59,164	35,788	23,376	60.5
2022	33	77,349	60,881	36,392	24,489	59.8
2023	39	76,392	62,688	44,515	18,173	71.0
2024	49	71,573	63,738	53,748	9,990	84.3
2025	66	122,374	104,237	89,008	15,229	85.4

Source: CMS analysis of IDR data for January enrollment for CY 2021 – 2025.

Over the last five years, California is the State with the largest number of C-SNPs with a high proportion of dually eligible individuals. Table FF3 details the growth of these C-SNPs in California. Dually eligible enrollment in these C-SNPs represents more than 90 percent of total enrollment. Of the 49 C-

SNPs and 66 C-SNPs nationally with 60 percent or more of total enrollment in CY 2024 and CY 2025, respectively, nearly half of these high proportion C-SNPs (24 in CY 2024 and 31 in CY 2025) were offered in California. The vast majority of dually eligible individuals enrolled in these C-SNPs were full-

benefit dually eligible individuals. Like C-SNP enrollment nationally, the California C-SNPs experienced a high degree of annual enrollment growth (98.7 percent increase) from CY 2024 (27,065 enrollees) to CY 2025 (53,786 enrollees).

TABLE FF3: C-SNPs WITH DUALY ELIGIBLE INDIVIDUALS REPRESENTING 60 PERCENT OR MORE OF THE TOTAL ENROLLMENT IN CALIFORNIA: CY 2021-2025

Year	Number of C-SNPs	Total C-SNP Enrollment	Total Dually Eligible Individual Enrollment in C-SNPs	Total Full-Benefit Dually Eligible Individual Enrollment in C-SNPs	Total Partial-Benefit Dually Eligible Individual Enrollment in C-SNPs	Dually Eligible Individual Enrollment as Percent of Total C-SNP Enrollment	Full-Benefit Dually Eligible Individual Enrollment as Percent of Total Dually Eligible C-SNP Enrollment
2021	10	12,154	11,044	10,889	154	90.9	98.6
2022	13	15,750	14,783	14,607	176	93.9	98.8
2023	17	20,571	19,898	19,744	154	96.7	99.2
2024	24	27,065	25,859	25,645	214	95.5	99.2
2025	31	53,786	51,367	51,144	223	95.5	99.6

Source: CMS analysis of IDR data for January enrollment for CY 2021 – 2025.

While Arizona and Illinois have substantially fewer C-SNPs with a high concentration of dually eligible individuals than California, C-SNPs in Arizona and Illinois also experienced sizable growth in enrollment from CY 2021 through CY 2025. In Arizona, enrollment in these C-SNPs with a high concentration of dually eligible individuals increased from zero enrollees in CY 2021 (zero C-SNPs) to 2,547 in CY 2025 (7 C-SNPs), with the highest level of annual growth (78.1 percent) occurring between CY 2023 (890 enrollees) and CY 2024 (1,585). These C-SNPs with a high proportion of dually eligible enrollees continued to grow (60.7 percent increase) between CY 2024 (1,585 enrollees) and CY 2025 (2,547 enrollees). Approximately 60

percent of dually eligible individuals enrolled in these C-SNPs are full-benefit dually eligible individuals.

In Illinois, C-SNPs with a high proportion of dually eligible individuals increased from 36 enrollees in CY 2021 (one C-SNP) to 41,218 enrollees in CY 2025 (6 C-SNPs), representing a growth of more than 3,180 percent. While the number of C-SNPs remained steady at 6 C-SNPs from CY 2024 to CY 2025, enrollment increased from 24,875 enrollees to 41,318 enrollees, a 66 percent increase. Nearly 85 percent of the dually eligible individuals enrolled in these C-SNPs are full-benefit dually eligible individuals.

New Mexico also experienced growth in C-SNPs with a high concentration of dually eligible individuals from CY 2021 (0 enrollees and 0 C-SNPs)

through CY 2025 (5,203 enrollees and 5 C-SNPs). Unlike California, Arizona, and Illinois, the C-SNPs in New Mexico lost enrollment from CY 2024 (7,582 enrollees) to CY 2025 (5,203 enrollees), a reduction of 31.4 percent, after annual increases from CY 2021 to CY 2024. Also, the proportion of full-benefit and partial-benefit dually eligible individuals enrolled in the C-SNPs has been approximately equal. We also note that Connecticut, Idaho, Illinois, New Hampshire, New Mexico, Oregon, and Vermont are States where dually eligible individuals comprise 60 percent or more of total C-SNP enrollment in 2025.⁸⁴

⁸⁴ CMS analysis of IDR data for January enrollment for 2025.

2. Growth in I-SNPs With High Proportion of Dually Eligible Enrollees

Compared to C-SNPs, the number of I-SNPs offered by MA organizations has remained relatively consistent in recent

years. As outlined in Table FF4, MA organizations offered 139 I-SNPs in CY 2021 and 144 I-SNPs in CY 2025 with an increase to 171 I-SNPs in CY 2023. I-SNP enrollment grew from 87,037 enrollees in CY 2021 to 121,188

enrollees in CY 2025, an increase of 39 percent. Dually eligible individuals represented the vast majority of I-SNP enrollees at approximately 90 percent of total enrollment each year.

TABLE FF4: I-SNPs AND THEIR ENROLLMENT: CY 2021 - 2025

Year	Number of I-SNPs	Total I-SNP Enrollment	Percent of Annual Growth in I-SNP Enrollment	Total Dually Eligible Individual Enrollment in I-SNPs	Percent of Annual Growth in Total Dually Eligible Individual Enrollment in I-SNPs	Total Dually Eligible Individual Enrollment as Percent of Total I-SNP Enrollment
2021	139	87,037		79,608		91.5
2022	156	96,230	10.6%	87,755	10.2	91.2
2023	171	105,992	10.1%	96,342	9.8	90.9
2024	164	117,964	11.3%	104,302	8.3	88.4
2025	144	121,037	2.7%	110,006	5.5	90.8

Source: CMS analysis of IDR data for January enrollment for CY 2021–2025.

For the most recent year reviewed (CY 2025), New York had the largest number of I-SNPs (12). The following other States had five or more I-SNPs in CY 2025: Florida (10); Ohio and Texas (8); North Carolina (7); California, Indiana,

Missouri, Oregon (6); and Arizona and Pennsylvania (5).

Table FF5 provides total I-SNP enrollment in the three I-SNP subtypes: FI-SNPs, HI-SNPs, and IE-SNPs for CY 2021 through CY 2025. On average over this time period, 73 percent of I-SNP

enrollees were beneficiaries enrolled in a FI-SNP (institutional-only), 22 percent were enrolled in a HI-SNP (institutional and institutional-equivalent) and 5 percent were enrolled in an IE-SNP (institutional-equivalent).

TABLE FF5: I-SNP ENROLLMENT BY PLAN TYPE AND DUAL ELIGIBLE STATUS: CY 2021 – 2025

Year	Enrollment in FI-SNPs			Enrollment in HI-SNPs			Enrollment in IE-SNPs		
	Total	Full	Partial	Total	Full	Partial	Total	Full	Partial
2021	67,225	65,263	136	17,019	12,263	185	2,619	1,609	53
2022	71,755	69,626	198	20,638	15,276	255	3,716	2,297	63
2023	76,172	73,871	260	24,302	18,631	300	5,399	3,166	77
2024	83,319	79,817	404	24,759	19,523	338	9,757	3,804	382
2025	85,749	82,312	368	29,609	23,792	286	5,679	3,141	107

Source: Data retrieved by CMS from Eligibility Enrollment Medicare Online in September 2025 for January enrollment for CY 2021–2025. The difference between total enrollment and sum of full-benefit and partial-benefit dually eligible individual enrollment reflects non-dually eligible individual enrollment in I-SNPs.

3. Challenges With C-SNPs and I-SNPs With High Proportion of Dually Eligible Enrollees

Dually eligible individuals encounter fragmentation in the health care system as they navigate the Medicare and Medicaid programs. CMS has been working to address these fragmented experiences through policies that integrate care for dually eligible individuals. Integrated care refers to delivery system and financing approaches that (1) maximize person-centered coordination of Medicare and Medicaid services; (2) mitigate cost-shifting incentives between the two programs; and (3) create a seamless experience for dually eligible individuals. Our efforts in recent years have increased opportunities for

enrollment in D-SNPs that are aligned with Medicaid managed care plans operated through a common parent organization (integrated D-SNPs).

The challenges with C-SNPs and I-SNPs enrolling high proportion of dually eligible individuals are similar to the challenges of D-SNP look-alikes. CMS established contracting limitations on D-SNP look-alikes at § 422.514(d) whereby CMS does not (a) enter into a contract for a new non-SNP MA plan that projects, in its bid submitted under § 422.254, that 60 percent or more of its enrollees are dually eligible or (b) renew a contract with a non-SNP MA plan that has 60 percent or more dually eligible enrollees. We established these contract limitations to address proliferation and growth of D-SNP look-alikes, which raised concerns related to effective

implementation of requirements for D-SNPs established by section 1859 of the Act (including amendments made by the Medicare Improvement for Patients and Providers Act of 2008 (Pub. L. 110–275) and the Bipartisan Budget Act of 2018 (Pub. L. 115–123)). As stated in the final rule titled “Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program,” which appeared in the **Federal Register** on June 2, 2020 (hereafter referred to as the June 2020 final rule; 85 FR 33805 through 33806), we adopted the D-SNP look-alike contracting limitations to ensure full implementation of requirements for D-SNPs, such as SMACs, a minimum integration of

Medicare and Medicaid benefits, care coordination through health risk assessments (HRAs), and evidence-based models of care (MOCs). These requirements promote coordination of care. Additionally, the SMAC requirement allows States the flexibility to require greater integration of Medicare and Medicaid benefits from the D-SNPs in their markets. For example, to develop products that integrate Medicare and Medicaid coverage, in CY 2025, 14 States (Arizona, California, District of Columbia, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Puerto Rico, Tennessee, Virginia, and Wisconsin) operate Medicaid managed care programs for dually eligible individuals in which the State requires that the Medicaid MCOs enrolling dually eligible individuals offer an affiliated D-SNP product and limit D-SNP enrollment in those plans to full-benefit dually eligible enrollees. The number of States with these requirements will increase in CY 2026 to include Indiana, Delaware, and several States (Illinois, Michigan, Ohio, Rhode Island, and South Carolina) previously participating in the Financial Alignment Initiative where Medicare-Medicaid Plans are transitioning to integrated D-SNPs effective January 1, 2026. Through their annual SMACs, these States are implementing intentional strategies to better coordinate care for dually eligible individuals. The analysis outlined earlier in this section shows that a number of these States (for example, California, Illinois, Arizona) have experienced increased growth in C-SNPs and increasing concentrations of dually eligible individuals in those C-SNPs in recent years.

C-SNPs could be serving as a workaround to Federal and State integration efforts. Among full-benefit dually eligible individuals newly enrolling in C-SNPs in January 2024 (40,048), 13.0 percent (5,206) were previously enrolled in plans with high-levels of Medicare-Medicaid integration (AIP D-SNPs, non-AIP FIDE SNPs, PACE, MMPs), 4.8 percent (1,902) were previously enrolled in D-SNPs with moderate-level integration (non-AIP HIDE SNPs), and 7.0 percent (2,808) were previously enrolled in D-SNPs with low-level integration (non-AIP coordination-only D-SNPs).⁸⁵ Among full-benefit dually eligible individuals newly enrolling in C-SNPs in January 2025 (68,554), 14.2 percent (9,732) were previously enrolled in plans with high-level integration (AIP D-SNPs, non-AIP

FIDE SNPs, PACE, MMPs), 4.4 percent (3,037) were previously enrolled in D-SNPs with moderate-level integration (non-AIP HIDE SNPs), and 8.9 percent (6,083) were previously enrolled in D-SNPs with low-level integration (non-AIP coordination-only D-SNPs). These data show a one-year increase of 71 percent in the number of full-benefit dually eligible individuals who were enrolled in a D-SNP, PACE plan, or MMP in January 2024 (40,048) vs. January 2025 (68,554) and enrolled in a C-SNP the next year. The highest percentage of these enrollees transitioned out of the plans with the highest level of Medicare-Medicaid integration. We note that other publications have analyzed these data.⁸⁶ For purposes of this analysis, we categorized plans as highly integrated based on presence of exclusively aligned enrollment, which may differ from estimates in other publications. The level of Medicare and Medicaid service integration in D-SNPs is also important.

Like D-SNPs, C-SNPs and I-SNPs must have approved MOCs and develop HRAs and individualized care plans (ICPs). C-SNPs and I-SNPs can offer benefits specific to chronic disease and institutionalization-level needs, respectively. In CY 2024, 84 percent of C-SNPs offered Special Supplemental Benefits for the Chronically Ill (SSBCI), with food and produce and general living support being the most common SSBCI offerings.⁸⁷ These benefits may be attractive to dually eligible individuals who have a higher prevalence of chronic conditions than non-dually eligible Medicare beneficiaries; 26 percent of dually eligible individuals have five or more chronic conditions, compared to 15 percent of Medicare beneficiaries without Medicaid coverage.⁸⁸ Dually eligible individuals are also more likely than non-dually eligible beneficiaries Medicare beneficiaries to live in an institution (11 percent vs. 3 percent) and report being in poor health (11

percent vs. 4 percent).⁸⁹ However, C-SNPs and I-SNPs are not subject to State contracting requirements applicable to D-SNPs nor do they reflect the key elements of integrated care: maximized person-centered coordination of Medicare and Medicaid services; mitigation of cost-shifting incentives between the two programs; and a seamless experience for dually eligible individuals. Although research has not yet uniformly shown an advantage for dually eligible individuals enrolling in plans with Medicare and Medicaid integration, preliminary evidence suggests that dually eligible individuals enrolled in integrated plans, on average, experience, reduced emergency department and inpatient hospital admissions, fewer long-term nursing facility stays, greater use of patient care, and slightly better experience and clinical outcomes than those in non-integrated plans.⁹⁰

C-SNPs and I-SNPs are currently exempt from the D-SNP look-alike contracting limitations. As stated in the June 2020 final rule (85 FR 33813) and April 2024 final rule (89 FR 30722), we excluded SNPs from evaluation against the prohibition on D-SNP look-alikes. Our rationale for the exclusion was to allow for the predominant dually eligible enrollment that characterizes D-SNPs, I-SNPs, and some C-SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. Nonetheless, we stated that we would monitor enrollment in other types of SNPs to assess whether such plans are structured primarily to serve dually

⁸⁹ MedPAC and MACPAC. Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid. January 2024. Exhibits 7 and 8. Available from: https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508.pdf.

⁹⁰ Roberts ET, Duggan C, Stein R, Jonnadula S, Johnston KJ, Figueroa JF. Quality, spending, utilization, and outcomes among dual-eligible Medicare-Medicaid beneficiaries in integrated care programs: a systematic review. JAMA Health Forum. July 2024. Available from: <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2821202>; Feng Z, Wang J, Gadaska A, Knowles M, Haber S, Ingber M, Grouverman, V. Comparing Outcomes for Dual Eligible Beneficiaries in Integrated Care: Final Report, September 2021. Available from: <https://aspe.hhs.gov/sites/default/files/documents/9739cab65ad0221a66ebe45463d10d37/dual-eligible-beneficiaries-integrated-care.pdf>; and <https://www.macpac.gov/wp-content/uploads/2019/07/Evaluations-of-Integrated-Care-Models-for-Dually-Eligible-Beneficiaries-Key-Findings-and-Research-Gaps.pdf>; and MACPAC Evaluations of Integrated Care Models for Dually Eligible Beneficiaries: Key Findings and Research Gaps, August 2020. Available from: <https://www.macpac.gov/wp-content/uploads/2019/07/Evaluations-of-Integrated-Care-Models-for-Dually-Eligible-Beneficiaries-Key-Findings-and-Research-Gaps.pdf>.

⁸⁶ For example, Stein R, Ma Y, Phelan J, Figueroa JF. Growth of C-SNPs May Be Jeopardizing Medicare-Medicaid Integration. Health Affairs. September 2025. Retrieved from: <https://www.healthaffairs.org/content/forefront/growth-c-snps-may-jeopardizing-medicare-medicaid-integration>.

⁸⁷ Milliman, Chronic Condition Special Needs Plans: 2024 Market Landscape and Future Consideration, April 2024. Available from: <https://www.milliman.com/en/insight/chronic-condition-special-needs-plans-2024-market-landscape>.

⁸⁸ KFF, A Profile of Medicare-Medicaid Enrollees (Dual Eligibles). January 2023. Available from: <https://www.kff.org/medicare/issue-brief/a-profile-of-medicare-medicaid-enrollees-dual-eligibles/>.

⁸⁵ CMS analysis of IDR data for CY 2023–2025.

eligible enrollees without meeting D-SNP requirements. In their comments on the November 2023 proposed rule (89 FR 30719), MACPAC suggested that we monitor growth in enrollment of dually eligible beneficiaries in other types of SNPs, including C-SNPs and I-SNPs, and identify any potential effects on integration efforts.

The number of D-SNP look-alikes transitioning enrollees to C-SNPs has increased in recent years. That increase could, at least in part, be driven by the exclusion of C-SNPs from the D-SNP look-alike prohibition. CY 2023 D-SNP look-alikes transitioned zero enrollees into C-SNPs effective for January 1, 2024. CY 2024 D-SNP look-alikes transitioned approximately 3,600 enrollees into 3 receiving C-SNPs effective for January 1, 2025. We expect the CY 2025 D-SNP look-alikes to transition approximately 16,500 enrollees into 8 receiving C-SNPs effective for January 1, 2026.

4. Potential Policy Changes for Comment Solicitation

We solicit comments on potential policy changes to support integrated care and improved health outcomes given the significant growth of dually eligible individuals enrolling in C-SNPs and I-SNPs.

First, we solicit comment on establishing a SMAC requirement similar to the existing requirement for D-SNPs. Under this idea, MA organizations seeking to offer a C-SNP or I-SNP with a high concentration of dually eligible individuals would need to have an executed contract with the State Medicaid agency that allows that plan to operate in the State during a particular contract year. Such a contract would allow States to proactively consider and coordinate their integration strategy for dually eligible individuals with the existence of such C-SNPs and I-SNPs enrolling a 60 percent or more dually eligible individuals. A State Medicaid agency contract for C-SNPs or I-SNP could include additional Federal or State-specific requirements similar to the D-SNP SMAC requirements at § 422.107. We solicit comments on whether or not we should adopt a SMAC requirement for C-SNPs and/or I-SNPs with high concentrations for dually eligible individuals as well as potential Federal requirements for those SMACs.

Second, we solicit comments on methods to increase care coordination for dually eligible individuals enrolled in C-SNPs and I-SNPs. Section 438.208 includes coordination and continuity of care requirements for Medicaid MCOs, PIHPs, and PAHPs. Many of the

requirements mirror the care coordination and MOC requirements for SNPs and closely involve the populations served by C-SNPs and I-SNPs. The requirement at § 438.208(a)(3)(i) states that for each Medicaid MCO that serves enrollees who are also enrolled in and receive Medicare benefits from an MA organization, the State determines to what extent the MCO must meet the identification, assessment, and treatment planning requirements for enrollees with special health care needs or who need long-term services and supports. These are the types of beneficiaries who, by definition per eligibility criteria at § 422.2, are enrolled in C-SNPs and I-SNPs.

While all SNPs must have approved MOCs, conduct HRAs, and develop ICPs, currently more care coordination requirements apply to D-SNP enrollees than C-SNP and I-SNP enrollees. For example, in the final rule titled “Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly”, which appeared in the **Federal Register** on April 15, 2025 (90 FR 15792) (hereinafter referred to as the April 2025 final rule), we amended § 422.101(f)(1)(v) to require that AIP D-SNPs conduct a single comprehensive HRA that meets the Medicaid requirements at § 438.208(b)(3) as well as Medicare requirements. In addition, we published MOC submission requirements for SNP MOC approval in the **Federal Register** (90 FR 26591; CMS-10565; OMB control number 0938-1296),⁹¹ which require D-SNPs to describe how the ICP coordinates Medicare and Medicaid services and, if applicable, provides those services, including long-term services and supports and behavioral health services, and describes how the D-SNP coordinates with providers of Medicaid-covered services during care transitions. We are considering whether to extend any of these existing D-SNP care coordination requirements to C-SNPs and I-SNPs given the high proportion of dually eligible individuals enrolled in these plans. We solicit comments on whether we should (a) adopt any new care coordination requirements for dually eligible C-SNP and/or I-SNP

enrollees; (b) add any MOC requirements for these SNP types; and (c) what those care coordination or MOC requirements should include.

Third, we solicit comment on three approaches to applying the D-SNP look-alike contracting limitations at § 422.514(d) through (g) to C-SNPs. Applying these contracting limitations would ensure that enrollees in C-SNPs with a significant proportion of dually eligible individuals would benefit from the requirements for integrated care that protect D-SNP enrollees. First, CMS could consider applying the D-SNP look-alike contracting limitations as is to C-SNPs and remove the current exemption on C-SNPs from the D-SNP look-alike contracting limitations at § 422.514(d) through (g). CMS would not (a) enter into a contract for any non-D-SNP or non-I-SNP MA plan that projects, in its bid submitted under § 422.254, that 60 percent or more of its enrollees are dually eligible or (b) renew a contract with any MA plan that has 60 percent or more dually eligible enrollees. Consistent with § 422.514(e), existing C-SNPs with 60 percent or more dually eligible individuals could transition enrollees to a D-SNP. Under a potential alternative approach, CMS could apply the D-SNP look-alike contracting limitations at § 422.514(d) through (g) to C-SNPs but exempt partial-benefit dually eligible individuals from the 60-percent threshold calculation. Partial-benefit dually eligible individuals do not have Medicaid benefits to coordinate with Medicare benefits in the same way as full-benefit dually eligible individuals, and the benefits that a C-SNP may offer could outweigh the role of Federal and State requirements outlined in a SMAC. We solicit comments on the potential approaches to apply the D-SNP look-alike contracting limitations as is to C-SNPs and excluding partial-benefit dually eligible individuals from the 60-percent threshold calculation.

We recognize that one of the challenges with these policy options is that many C-SNPs do not have a D-SNP in the same service areas as the C-SNP, which could lead to a large proportion of C-SNP enrollees transitioning to a non-SNP MA plan or Original Medicare and a standalone Part D plan. Exempting partial-benefit dually eligible individuals from the 60-percent threshold calculation could reduce the number of C-SNPs subject to transition. Another approach for consideration would be to exempt C-SNPs from the 60-percent threshold in States that do not have any integrated D-SNPs (that is, FIDE SNPs, HIDE SNPs, or AIPs), targeting it to States with Medicare-

⁹¹ CMS, Model of Care Submission Requirements, June 23, 2025. Retrieved from: <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/prior-listing-items/cms-10565>.

Medicaid integration strategies. Thus, C-SNPs could continue in States with D-SNPs meeting the minimum integration requirements. If this potential policy proposal applied in CY 2025, that would mean we would not apply the 60-percent threshold to C-SNPs in the following 24 States: Alabama, Arkansas, Colorado, Connecticut, Delaware, Georgia, Iowa, Louisiana, Maryland, Michigan, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nevada, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Utah, West Virginia, and Wyoming. We expect some of these States (Delaware, Michigan, Ohio, Rhode Island, and South Carolina) to establish SMACs with integrated D-SNPs for CY 2026 as well as Illinois which is contracting with D-SNPs for the first time in several years. We welcome comments on the benefits and challenges of C-SNP enrollees transitioning to non-SNP MA plans and Original Medicare and a standalone Part D plan as well as other suggestions for potential transitions.

Fourth, we request that stakeholders submit for our consideration any other policy suggestions that could help ensure that there are appropriate protections in place to support high-quality, integrated care for dually eligible enrollees given the increasing proportion of them enrolling in C-SNPs and I-SNPs.

Fifth, we welcome comments on the policy ideas outlined in this section to help inform potential future regulatory action. Also, we are monitoring the performance of D-SNPs, C-SNPs, and I-SNPs on quality metrics and differences in Medicare supplemental benefits provided and expect to have more comparable quality and benefits information available within the next year to further inform policymaking. We welcome commenters to share any evidence they have on comparable quality and benefits information for consideration as well.

Finally, CMS is also interested in how to support improved access to treatment and care coordination for individuals with mental health conditions or substance use disorders as we believe SNPs could be situated to perform a critical role in supporting the improvement of care provided to individuals with serious mental illness (SMI). In particular, C-SNPs offer plans focused on chronic conditions such as chronic alcohol and other drug dependence and chronic and disabling mental health conditions (42 CFR 422.4(a)(1)(iv)(B)). However, despite the growth in C-SNPs, CMS has observed that few MA organizations have

sponsored C-SNPs focusing on these categories since the beginning of the program, with only two Chronic Mental Health C-SNPs that serve 2,646 enrollees in Florida and California currently operating as of September 2025.⁹² We invite public comment on the difficulties of creating C-SNPs focused on these conditions, as well as recommended incentives, outcome-based measures, or strategies that would make it easier for MA plans to design and offer these plans. In addition, we welcome comments on how other SNP types, such as D-SNPs and I-SNPs, are serving this population and what improvements could be made to ensure individuals with SMI are connected to appropriate services. We also invite comments on the advantages and disadvantages of dually eligible individuals with SMI receiving care through enrollment in a C-SNP where we would expect extra emphasis on addressing mental health needs versus through enrollment in a D-SNP that would coordinate Medicare and Medicaid benefits that may also be helpful in addressing mental health needs. Finally, CMS welcomes commenters to share any other considerations or regulatory changes they believe may be necessary to support the availability of high-quality SNPs to serve individuals with SMI.

VII. Reducing Regulatory Burden and Costs in Accordance With Executive Order (E.O.) 14192

As noted previously, we are seeking public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. Please refer to the RFI at <https://www.cms.gov/medicare-regulatory-relief-rfi> and submit all comments via this link.

A. Exclusion of Account-Based Medical Plans From Entities Required To Make Disclosures of Creditable Coverage (§ 423.56)

Section 1860D–13(b)(6)(B)(i) of the Act provides that each entity that offers prescription drug coverage of the type described in subparagraphs (B) through (H) of section 1860D–13(b)(4) of the Act shall provide for disclosure, to the Secretary and Part D eligible individuals, of whether the coverage is creditable coverage, that is, equals or

exceeds the actuarial value of standard prescription drug coverage (as determined under section 1860D–11(c) of the Act), or whether such coverage is changed so it no longer meets such requirement. Section 1860D–13(b)(6)(B)(ii) of the Act requires such entities to disclose if coverage does not meet such requirement, and that the disclosure to Part D eligible individuals shall include information that there are limitations on the periods in a year in which the individual may enroll in Part D coverage, and that any such enrollment is subject to a Part D late enrollment penalty (LEP). In addition, section 1860D–13(b)(4)(H) of the Act provides the Secretary with the flexibility to identify “other coverage” that could be considered creditable coverage. The types of coverage that are subject to the creditable coverage requirements and the procedures to determine and document creditable status of prescription drug coverage were codified at § 423.56 in the final rule entitled “Medicare Program; Medicare Prescription Drug Benefit (Part D final rule)” that appeared in the January 28, 2005, **Federal Register** (70 FR 4532).⁹³

Section 1860D–13(b)(4)(C) of the Act includes Group Health Plans (GHPs) as entities that are required to provide creditable coverage disclosures. The statute states that GHPs include health benefits plans under chapter 89 of title 5 (commonly known as the Federal Employees Health Benefits Program) and qualified retiree prescription drug plans as defined at section 1860D–22(a)(2) of the Act. The term, “Group Health Plan” was codified at § 423.882 in the 2005 Part D final rule (70 FR 4577),⁹⁴ and this definition includes account-based medical plans such as health reimbursement arrangements (HRAs) as defined in Internal Revenue Service (IRS) Notice 2002–45, 2002–28 I.R.B. 93, health Flexible Spending Arrangements (FSAs) as defined in Internal Revenue Code (Code) section 106(c)(2), health savings accounts (HSAs) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b) (29 U.S.C. 1003(b)) for governmental plans or church plans).

⁹² SNP Comprehensive Report for September 2025. Retrieved from: <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/special-needs-plan-snp-data/snp-comprehensive-report-2025-09>.

⁹³ <https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit>.

⁹⁴ <https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit>.

Section 1860D–13(b)(6)(B)(i) of the Act requires “entities that offer prescription drug coverage” to provide for these creditable coverage disclosures to the Secretary and Part D eligible individuals, but account-based plans (for example, HRAs, FSAs, HSAs, etc.) do not actually offer prescription drug coverage; rather, they are arrangements created by employers and designed to provide individuals savings on healthcare costs through pre-tax contributions and reimbursements, that are often provided to supplement other coverage, such as another group health plan or individual market coverage. Therefore, the benefit design of account-based plans makes concepts, such as disclosure of creditable coverage, inapplicable to those arrangements.

As an example, HRAs,⁹⁵ which are arrangements that are paid solely by the employer, reimburse employees only for their, their spouse’s, and their dependents’ medical care expenses⁹⁶ (including premiums), provide reimbursements up to a maximum dollar amount, and carry forward unused balances in the arrangement from one year to the next. Individual Coverage HRAs (ICHRAs), which were more recently recognized by the Labor, Health and Human Services, and Treasury Departments in the June 20, 2019 final rule titled, “Health Reimbursement Arrangements and Other Account-Based Group Health Plans” (84 FR 28888),⁹⁷ are also a type of reimbursement arrangement; however, to receive reimbursements for medical care expenses from an ICHRA, employees and any covered dependents must actually be enrolled in individual health insurance coverage or Medicare Parts A and B, or Part C.

HRAs, including ICHRAs, are group health plans that are not, as section 1860D–13(b)(6)(B)(i) of the Act requires, entities that offer prescription drug coverage. Comparing a reimbursement arrangement, such as an HRA, against the intricacies of a prescription drug plan, including whether the reimbursement provided equates to coverage that would be considered creditable (that is, offers coverage at least as good as the Medicare standard drug benefit), is not an ‘apples to apples’

comparison because account-based plans are fundamentally different from prescription drug plans. While account-based plans generally only provide a financial benefit to employees, for example, tax savings, prescription drug coverage conveys numerous benefits to beneficiaries.

As discussed previously, section 1860D–13(b)(6)(B)(i) of the Act requires that “entities that offer prescription drug coverage” must provide creditable coverage disclosures. Under that requirement, we propose that account-based entities, which do not offer such coverage, are not required to provide the creditable coverage disclosures. Requiring account-based plans, such as HRAs, including ICHRAs, to determine if their coverage is creditable, and requiring them to report the creditable status of that coverage, unduly increases administrative burden on these entities by causing them to expend additional resources and expertise that they may not possess. If these entities disclose that they do not offer creditable coverage (because they do not directly offer prescription drug coverage), and the individual’s plan that directly offers the prescription drug benefit coverage discloses that the benefit is creditable, this could result in an individual receiving potentially contradictory and confusing information. Ultimately, this confusion disadvantages the Part D Medicare-eligible individual in their ability to make an informed choice about their prescription drug coverage, and ensuring that beneficiaries receive clear information is crucial. Moreover, as the number of account-based plans has grown in recent years, we have received feedback from organizations who offer these products that they believe the requirement to report creditable coverage does not comport with the account-based model. This proposal to exclude account-based plans from making these disclosures is a possible solution to address the feedback we have received from the industry, as it will provide clarity and ensure consistency for Medicare-eligible individuals as well as other industry interested parties. This proposal also aligns with the President’s January 31, 2025, Executive Order (E.O.), titled *Unleashing Prosperity Through Deregulation*, as, if finalized, it would eliminate the need to acquire and maintain resources and expertise to comply with federal regulations to provide creditable coverage disclosures.

Therefore, we are proposing to modify regulations at § 423.56(b)(3) to codify that account-based plans, such as HRAs and ICHRAs, are excluded from group

health plans that are required to make creditable coverage disclosures.

B. Deregulate § 422.102(e) Pathway for Certain D–SNPs To Offer Supplemental Benefits (§ 422.102)

We provide several avenues for MA plans to provide enrollees with supplemental benefits. In the final rule titled “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes,” which appeared in the **Federal Register** on April 12, 2012 (hereafter referred to as the April 2012 final rule), we codified § 422.102(e). As we described in the preamble to the April 2012 final rule (77 FR 22075), § 422.102(e) specifies that, subject to our approval, and as specified annually by us, certain D–SNPs that meet integration and performance standards may offer additional Medicare supplemental benefits beyond those we currently allowed other MA plans to offer at the time of publication, where we find that the offering of such benefits could better integrate care for the dual eligible population. Such benefits may include nonskilled nursing services, personal care services, and other long-term care services and supports designed to keep dual eligible beneficiaries out of institutions.

In the Announcement of CY 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter issued on April 2, 2018, we announced its expanded interpretation of the “primarily health related” standard applied to supplemental benefits in light of section 1852(a)(3) of the Act, which requires supplemental benefits to be “health care benefits.” Under the expanded interpretation, for an item or service to be considered as primarily health related, it must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. In the call letter, we expressed the belief that the expanded standard for “primarily health related” provided MA plans with more flexibility in designing and offering supplemental benefits that can enhance beneficiaries’ quality of life and improve health outcomes.⁹⁸ We note that CMS codified this standard at § 422.100(c)(2)(ii)(A).

⁹⁸ CMS, Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final

⁹⁵ HRAs were first recognized in 2002 in guidance—Internal Revenue Service (IRS), “Health Reimbursement Arrangements,” Notice 2002–45, at <https://www.irs.gov/pub/irs-drop/n-02-45.pdf>.

⁹⁶ IRC § 213; IRS, “Medical and Dental Expenses,” Publication 502, January 11, 2022, at <https://www.irs.gov/pub/irs-pdf/p502.pdf>; and IRS, *Health Savings Accounts and Other Tax-Favored Health Plans*, IRS Publication 969, February 11, 2021, p. 18, at <https://www.irs.gov/pub/irs-pdf/p969.pdf>.

⁹⁷ <https://www.govinfo.gov/app/details/FR-2019-06-20/2019-12571>.

Additionally, the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 1852(a) of the Act to expand the types of supplemental benefits that may be offered by MA plans to chronically ill enrollees, called special supplemental benefits for the chronically ill (SSBCI). We codified the parameters for SSBCI at § 422.102(f) in the June 2020 final rule. (85 FR 33800) SSBCI includes supplemental benefits that are not primarily health related and may be offered non-uniformly to eligible chronically ill enrollees. MA plans can offer a “non-primarily health related” item or service to chronically ill enrollees if the SSBCI has a reasonable expectation of improving or maintaining

the health or overall function of the chronically ill enrollee.

In recent years, few MA plans have used § 422.102(e) to provide supplemental benefits, as shown in Table G–B 1. Our analysis of the bid data from 2013 to 2026, as seen in Table G–B 1, shows that the supplemental benefits D–SNPs have offered through § 422.102(e) are meals benefits and assistive devices for home safety. We note that these benefits can currently be covered under the expanded definition of primarily health related supplemental benefits and SSBCI. Specifically, the April 2019 HPMS memo titled “Implementing Supplemental Benefits for Chronically Ill Enrollees” refers to Chapter 4 of the Medicare Managed Care

Manual that indicates that meals are a primarily health related supplemental benefit (PBP category B13c) in limited situations: when provided to enrollees for a limited period immediately following surgery, or an inpatient hospitalization, or for a limited period due to a chronic illness. In those situations, a meals supplemental benefit is permissible if the meals are: (1) needed due to an illness; (2) consistent with established medical treatment of the illness; and (3) offered for a short duration. Meals may be offered beyond a limited basis as a non-primarily health related supplemental benefit (PBP category B19b/13i) to chronically ill enrollees. Meals may be home-delivered and/or offered in a congregate setting.⁹⁹

TABLE G-B 1: SUPPLEMENTAL BENEFITS OFFERED THROUGH § 422.102(e) FOR CONTRACT YEARS 2013 TO 2026

Contract Year	# of D-SNP PBPs Offering Benefits	Supplemental Benefits Offered
2026	0	None
2025	2	Meals provided to members with a chronic condition
2024	2	Meals provided to members with a chronic condition
2023	2	Additional meal delivery
2022	2	Additional meal delivery
2021	1	Additional meal delivery
2020	1	Additional meal delivery
2019	2	Additional meal delivery, Assistive devices for home safety
2018	2	Additional meal delivery, Assistive devices for home safety
2017	0	None
2016	0	None
2015	0	None
2014	0	None
2013	2	Safety assessment / home adaptation

Source: HPMS

We believe the small number of D–SNPs offering supplemental benefits through § 422.102(e) is due to the availability of other pathways to provide the same supplemental benefits that can be covered under § 422.102(e). Based on this experience, we believe that § 422.102(e) is no longer needed and propose to remove and reserve § 422.102(e) for future rulemaking. The two D–SNPs offering supplemental benefits through § 422.102(e) in CY 2025 have 27,888 enrollees as of June 2025.

For CY 2026, no plan requested to offer supplemental benefits through § 422.102(e). We do not anticipate any adverse consequences to removing § 422.102(e) since D–SNPs could offer the same benefits in their annual bid through primarily health related supplemental benefits or SSBCI. By comparison, 905 MA plans offered supplemental benefits through SSBCI in CY 2025. Of those 905 MA plans, 45 plans offered limited meals benefits (four of which were D–SNPs), and 229

MA plans offered meals beyond a limited basis (71 of which were D–SNPs).

We do not anticipate this proposal will add burden to plans given the small number of D–SNPs utilizing the § 422.102(e) pathway. Also, given primarily health related supplemental benefits and SSBCI are the more common pathways for offering supplemental benefits, deregulating § 422.102(e) could streamline the bid submission process for D–SNPs and us

Call Letter, page 208. Retrieved from: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>.

⁹⁹ CMS, HPMS Memorandum, “Implementing Supplemental Benefits for Chronically Ill Enrollees”. Retrieved from: <https://www.cms.gov/research-statistics-data-and-systems/computer->

[data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2019-week4-apr-22-26](https://www.cms.gov/research-statistics-data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2019-week4-apr-22-26).

by simplifying the avenues for offering supplemental benefits.

We solicit comments on our proposal. We request that commenters consider whether there is any value to us retaining § 422.102(e), such as whether there are any Medicare supplemental benefits that could only be offered under § 422.102(e) and not through primarily health related supplemental benefits or SSBCI. We also recognize that participating D-SNPs will no longer be able to offer benefits through the MA Value-Based Insurance Design (VBID) model beginning in CY 2026 and solicit comments on whether § 422.102(e) provides any advantages in D-SNPs offering supplemental benefits previously offered under VBID.

C. Rescind Mid-Year Supplemental Benefits Notice (§§ 422.111(l) and 422.2267(e)(42))

The “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)” final rule appeared in the April 23, 2024 **Federal Register** (89 FR 30448), hereinafter referred to as the April 2024 final rule, which included a new requirement, beginning January 1, 2026, that MA organizations must notify enrollees mid-year of any unused supplemental benefits available to them (89 FR 30448, 30561). The notice, referred to as the Mid-Year Notice, would list any supplemental benefits not utilized by the enrollee during the first 6 months of the plan year.

The Mid-Year Notice was intended to address what appeared to be a gap in enrollee awareness and utilization of supplemental benefits for which MA organizations designate rebate dollars. After further review of interested parties’ feedback and more current data on supplemental benefit utilization (as described later in this proposal), CMS has determined that the frequency of utilization was higher than previously believed. In addition, CMS has concerns about the administrative and financial burden, especially on smaller MA organizations, and believes this new requirement is duplicative of already existing requirements. As a result, via the agency’s authority to establish standards consistent with, and to carry out, Part C under section 1856(b)(1) of the Act, CMS proposes to rescind the

Mid-Year Notice of Supplemental Benefits requirement established in §§ 422.111(l) and 422.2267(e)(42), that requires MA organizations to provide annual mid-year notices to enrollees regarding unused supplemental benefits.

Rescission of this requirement is consistent with E.O. 14192, “Unleashing Prosperity through Deregulation.” E.O. 14192 instructed federal agencies to review all regulations to alleviate unnecessary regulatory burdens placed on the American people. CMS has reviewed this regulation in accordance with E.O. 14192 and determined that this requirement is unnecessary for the reasons outlined in this section. The Mid-Year Notice would impose a significant burden on MA organizations that outweighs the intended benefit. As documented in the April 2024 final rule responses to public comments, MA organizations expressed numerous concerns about the burden and complexity of compliance. The requirement necessitates the development, implementation, and maintenance of tracking systems to monitor individual enrollee utilization of each supplemental benefit from January 1st to June 30th of the plan year. It also requires MA organizations to compile and send the individualized information to each corresponding enrollee in paper format between June 30th and July 31st of the plan year, providing about a 1-month window to mail information to potentially millions of enrollees. Additionally, MA organizations have stated that they predict the substantial task of printing and mailing several pages of individualized documents within a compressed time frame would exceed CMS’s original estimate for administrative costs. The impact would be substantially higher for smaller MA organizations and could contribute to competitive disadvantages that result in reduced plan choice for MA enrollees.

Further, with respect to MA organizations of all sizes, the administrative complexity and operational costs associated with meeting the Mid-Year Notice requirement would consume resources that could be better utilized for activities with more direct impact on enrollee health outcomes and satisfaction. Instead, the Mid-Year Notice risks diversion of organizational capacity away from more beneficial work such as patient care coordination or quality improvement activities—both of which are required under statute.

Another factor considered in this proposal is the unnecessary duplication of information already provided to

enrollees through existing statutory disclosure requirements. Section 1852(c)(1) of the Act requires MA organizations to provide detailed descriptions of all plan provisions, including supplemental benefits, in a clear, accurate, and standardized form through the Evidence of Coverage (EOC) document. MA organizations must furnish this information to enrollees at the time of enrollment and annually thereafter. As specified in regulation at § 422.2267(e)(42), the Mid-Year Notice must include, for each unused mandatory and optional supplemental benefit, the information that appears for those benefits, in the EOC. The Mid-Year Notice would therefore be redundant of information that enrollees already received about their benefits no more than 6 months earlier.

Finally, the original justification for implementing the Mid-Year Notice requirement is not supported by the most current evidence available. In a recent survey¹⁰⁰ of 1,846 MA enrollees, 70 percent of respondents reported they had used at least one supplemental benefit in the past year; 19 percent reported they did not use their supplemental benefits because they did not need them. These findings suggest enrollees are generally aware of their supplemental benefits and are utilizing them, although CMS acknowledges that at this time, information on MA enrollee use of supplemental benefits is limited.

Market competition naturally incentivizes MA organizations to ensure enrollees are aware of and utilize the supplemental benefits that differentiate their plans. MA organizations have demonstrated that they can effectively promote awareness and utilization of supplemental benefits through existing channels. Moreover, a requirement to send additional information to enrollees, promoting benefits they will not necessarily be eligible for, could lead to enrollee confusion. Current care coordination activities, existing communication requirements, and proactive, voluntary outreach programs have proven successful in promoting supplemental benefit utilization. The particular regulatory requirement for a Mid-Year Notice would likely not result in improved communication of supplemental benefits information and could create undue burden for MA organizations. Further, recent evidence suggests that enrollees are utilizing supplemental benefits when they need them. Therefore, CMS proposes to rescind the Mid-Year Notice

¹⁰⁰ <https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage>.

requirement at §§ 422.111(l) and 422.2267(e)(42).

CMS welcomes comments on the rescission of this regulatory requirement.

D. Revisions to Ensuring Equitable Access to Medicare Advantage (MA) Services (§ 422.112(a)(8))

Under § 422.112(a)(8), MA organizations are required to ensure that services are provided in a culturally competent manner to all enrollees. In the final rule titled “Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” (88 FR 22120) (hereinafter referred to as the April 2023 final rule), CMS retitled the paragraph heading from “Cultural considerations” to “Ensuring Equitable Access to Medicare Advantage (MA) Services” and added more populations to the existing list of groups in the regulation. These changes were implemented in accordance with the previous administration’s E.O. 13985: “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” (E.O. 13985) issued on January 20, 2021. CMS explained in the preamble that the list of populations was clarifying in nature, non-exhaustive, and was intended to provide additional examples of populations MA organizations should be mindful of in their plan designs. CMS emphasized that the protections of the provision were already in effect prior to the proposed change and that MA organizations must provide all enrollees, without exception, accommodations to access services (88 FR 22152 and 22153). CMS determined there was no additional regulatory impact to MA organizations in terms of burden, resources for implementation, or collection information as MA organizations were already held to and in compliance with these requirements.

On January 20, 2025, E.O. 14148: “Initial Rescissions of Harmful Executive Orders and Actions” was issued and revoked E.O. 13985. E.O. 14148 states the “previous administration embedded deeply unpopular, inflationary, illegal, and radical practices within every agency and office of the Federal Government. The injection of ‘diversity, equity, and inclusion’ (DEI) into our institutions has corrupted them by replacing hard work, merit, and equality with a divisive and dangerous preferential hierarchy.” Additionally, on January 31, 2025, President Trump issued E.O. 14192,

“Unleashing Prosperity through Deregulation” which instructed Federal agencies to review regulations in their jurisdiction to alleviate unnecessary regulatory burdens placed on the American people. CMS has reviewed § 422.112(a)(8) in accordance with E.O.s 14148 and 14192 and determined that the revisions made in the April 2023 final rule were unnecessary as they did not change the underlying requirements for MA organizations and the modification of the regulatory text created additional and unnecessary complexity in interpreting the provision. As such, CMS is proposing to amend the regulation at § 422.112(a)(8) to revert to the prior paragraph heading and text which reads, “*Cultural considerations*. Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.” This proposed change will streamline the regulatory text and avoid confusion about the list of different sub-populations in implementation, while maintaining the protections for access to services for all enrollees.

CMS invites comments on this proposal.

E. Rescinding the Annual Health Equity Analysis of Utilization Management Policies and Procedures (§ 422.137(c)(5), (d)(6) and (d)(7))

The final rule titled “The Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” appeared in the April 12, 2023 **Federal Register** (88 FR 22120) (hereinafter referred to as the April 2023 final rule). The April 2023 final rule required that MA plans establish a Utilization Management (UM) Committee to annually review all UM policies and procedures, including for the use of prior authorization, and ensure that these policies are consistent with the coverage requirements, including Original Medicare’s current national and local coverage decisions and guidelines.

Then, in November 2023, CMS issued the Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (88 FR

78476) notice of proposed rulemaking (hereinafter referred to as the November 2023 proposed rule) wherein CMS proposed additional requirements related to the UM Committee. Specifically, at § 422.137(c)(5) CMS proposed a requirement that beginning in 2025, the UM Committee must include at least one member with “expertise in health equity.” In addition, at § 422.137(d)(6), CMS proposed a requirement that the UM Committee must conduct an annual health equity analysis of the use of prior authorization by examining the impact of prior authorization at the plan level, on enrollees with one or more specified Social Risk Factors (SRFs), defined as (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE) or (2) disability status, by reporting specific metrics aggregated for all items and services. Finally, CMS proposed a requirement at § 422.137(d)(7) that by July 1, 2025, and annually thereafter, this analysis must be posted on the plan’s publicly available website.

In response to the November 2023 proposed rule, CMS received a significant number of comments regarding concerns about the annual health equity analysis. Commenters expressed concerns there was not sufficient evidence that adding a role to the UM Committee would improve health equity. Some commenters indicated that prior authorization denial rates are not necessarily attributable to or correlated with an enrollee’s SRF status. Other commenters cautioned that some of the information gathered as part of this type of analysis may be confidential or proprietary to the MA plan. Overall, interested parties raised concerns about the rationale, feasibility, and administrative burden associated with meaningful implementation of the regulatory requirements.

In April 2024, CMS issued the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) final rule (89 FR 30448) (hereinafter referred to as the April 2024 final rule) and finalized new requirements related to the UM Committee. In response to comments, CMS took the position that while changes to the health equity analysis requirement would be helpful to provide a more in-depth analysis, the

health equity analysis requirement as proposed and finalized would provide useful baseline of data. CMS also signaled the intent to consider further changes to these requirements in subsequent rulemaking based on comments received.

The proposed rule titled “Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” appeared in the December 10, 2024 **Federal Register** (89 FR 99340). CMS proposed at § 422.137(d)(6)(iii)(A) through (H) to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the metrics to be reported by each item or service, rather than aggregated for all items and services. Many commenters expressed concerns that the expanded analysis requirements could be misrepresented due to the complexity of the disaggregated data and variance in plan sizes. Several commenters also stated the proposed policy change would be costly and burdensome for MA organizations. CMS did not finalize the proposal to expand the annual health equity analysis of UM policies and procedures.¹⁰¹

CMS implemented the additional UM Committee requirements in the April 2024 final rule based on the previous administration’s health equity related initiatives. Specifically, the regulatory requirements were implemented in accordance with feedback from interested parties, based on research, and the prior administration’s E.O. 13985: “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” issued on January 20, 2021.¹⁰² This E.O. has since been revoked by E.O. 14148: “Initial Rescissions of Harmful Executive Orders and Actions,”¹⁰³ which states the “previous administration has embedded deeply unpopular, inflationary, illegal, and radical practices within every agency and office of the Federal Government. The injection of ‘diversity, equity, and inclusion’ (DEI) into our institutions has corrupted them by replacing hard work,

merit, and equality with a divisive and dangerous preferential hierarchy.”

The health equity requirements implemented in the April 2024 final rule increased regulatory burden for MA organizations by requiring the addition of a member of the UM Committee with expertise in health equity, additional data collection, and the public posting of an annual health equity analysis. The increased regulatory burden is inconsistent with E.O. 14192, “Unleashing Prosperity Through Deregulation,” issued on January 31, 2025,¹⁰⁴ which seeks to address the significant burden that complex Federal regulations impose on Americans, which may hinder economic growth, innovation, and global competitiveness. E.O. 14192 states, “It is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people.”

Since the issuance of the April 2024 final rule, the CMS position on the health equity analysis requirement has changed. CMS now believes that this analysis is not the best vehicle to obtain baseline data on the use of prior authorization and that there are more effective ways to gain this information, including through robust interoperability efforts. CMS will continue to explore ways to collect data regarding the use of prior authorization in a manner that best represents all MA enrollees. CMS is taking steps to reduce the regulatory burdens imposed by the UM Committee requirements implemented in the April 2024 final rule consistent with the focus on streamlining regulations and reducing administrative burdens for those participating in the Medicare program. In response to interested parties concerns about the limited impact on health equity, the questionable utility of the required data analysis, and the additional administrative burden, deregulating the requirements at § 422.137(c)(5), (d)(6), and (d)(7) aligns with CMS policy goals and E.O.s 14148 and 14192.

Additionally, on June 16, 2025, CMS released a Health Plan Management System (HPMS) memorandum exercising enforcement discretion regarding the requirements under § 422.137(c)(5), (d)(6) and (d)(7) until further notice. As explained in the HPMS memorandum, CMS received numerous questions and requests for

guidance regarding the implementation of the requirements and determined that a temporary pause in enforcement was necessary to reevaluate the requirements and consider potential changes. CMS now proposes to remove the requirement at § 422.137(c)(5) that the UM Committee includes at least one member with expertise in health equity. In addition, CMS proposes to remove § 422.137(d)(6), which requires that the UM Committee conduct an annual health equity analysis of the use of prior authorization. Finally, CMS proposes to remove § 422.137(d)(7), which requires the health equity analysis to be posted on the plan’s website in a prominent manner that is publicly accessible.

In summary, CMS is proposing to rescind the requirements for MA organizations’ UM Committees at § 422.137(c)(5), (d)(6) and (d)(7), consistent with the cited E.O.s. and in response to interested parties concerns about the requirements’ rationale, feasibility, and administrative burden. This proposal aligns with CMS’ broader regulatory approach, including the decision not to finalize proposed expansions to the health equity analysis requirements in the April 2025 final rule.

CMS welcomes comments on this proposal. CMS also requests comments on ways to reduce administrative burdens associated with other UM Committee requirements for consideration in future rulemaking, including, but not limited to, recommendations on the following:

- Whether CMS should revise UM Committee composition requirements, including that members represent various clinical specialties; and
- Whether CMS should revise the UM Committee responsibilities, including the UM Committee’s role in the implementation of internal coverage criteria.

CMS is particularly interested in policy solutions that eliminate redundant reporting, reduce unnecessary requirements, and minimize duplicative processes to address inefficiencies and reduce financial burdens. More broadly, CMS welcomes suggestions for deregulating, simplifying, and streamlining MA organization governance requirements in ways that benefit enrollees, health care providers, suppliers, and MA organizations while ensuring continued delivery of high-quality care to Medicare beneficiaries.

¹⁰¹ 90 FR 15792, 15795.

¹⁰² <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>.

¹⁰³ <https://www.federalregister.gov/documents/2025/01/28/2025-01901/initial-rescissions-of-harmful-executive-orders-and-actions>.

¹⁰⁴ <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

F. Rescinding the Quality Improvement Program Health Disparities Requirement (§ 422.152(a)(5))

In accordance with section 1852(e) of the Act, all MA organizations must have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to enrollees. QI program requirements appear at 42 CFR 422.152. In April 2023, the “Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule” appeared in the **Federal Register** (88 FR 22120), hereinafter referred to as the April 2023 final rule. In the April 2023 final rule, CMS added a requirement at § 422.152(a)(5) that directs MA organizations to incorporate one or more activities that reduce disparities in health and health care as part of their QI program to comply with health equity mandates stemming from E.O. 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”

On January 20, 2025, E.O. 14148, “Initial Recission of Harmful Executive Orders and Actions,” revoked several executive orders, including E.O. 13985. Additionally, on January 31, 2025, E.O. 14192, “Unleashing Prosperity Through Deregulation,” was issued to address the significant burden that complex Federal regulations impose on Americans, and hinder economic growth, innovation, and global competitiveness. E.O. 14192 states, “It is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people.”

Consistent with E.O.s 14148 and 14192, CMS propose to eliminate the regulatory requirement for QI programs under § 422.152(a)(5), which reads in full, “Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.” The provision at § 422.152(a)(5) is not aligned with E.O. 14148 because it mandates race and ethnicity-conscious health equity activities that were originally implemented in accordance with E.O.

13985’s racial equity requirements, which E.O. 14148 explicitly revoked as part of its directive to eliminate federal programs and policies that prioritize considerations based on race, ethnicity, and other demographic characteristics.

With E.O. 14148’s elimination of federal policies to promote “diversity, equity, and inclusion,” the requirement to “incorporate one or more activities that reduce disparities in health and health care” no longer aligns with current administrative priorities. Moreover, CMS will retain the QI Program requirements under § 422.152(a)(1) through (4) to meet the requirements of section 1852(e) of the Act. The statute is clear and no further regulatory language to specify reducing health disparities is necessary to carry out the QI program. Additionally, this proposal aligns with the directives of E.O. 14192, to deregulate and reduce the administrative burden on MA organizations while preserving quality.

When this regulation was proposed, CMS received public comments asserting that some MA organizations were already addressing disparities in care for underserved populations through a variety of quality initiatives without the need for regulation. If this requirement is repealed as proposed, MA organizations would retain the flexibility to implement quality initiatives that address the needs of all enrollees, including the option to continue their current QI program or otherwise make their own determinations regarding whether and how to target health disparities. This will ensure services are delivered with equal dignity and respect to each individual and that MA organizations are not required to direct federal resources towards services limited to specific mandated subsets of enrollees. This proposed deregulation reflects CMS’s continued commitment to high-quality health care, while reducing unnecessary administrative burden associated with the prior regulatory requirements, including those established under earlier directives that prioritized narrow equity-focused initiatives driven by exclusively equity-focused executive orders.

CMS invite comments on this proposal.

G. Deregulate Special Rule for Non-Compliant D-SNPs (§ 422.752)

The Bipartisan Budget Act of 2018 (BBA of 2018; Pub. L. 115–123) amended section 1859 of the Act to establish new minimum standards for all D-SNPs related to integration with Medicaid services (section 1859(f)(8)(D)(i) of the Act). The BBA of

2018 also amended section 1859 of the Act to authorize the Secretary to impose an enrollment sanction on an MA organization offering a D-SNP that has failed to meet at least one of the new integration standards in plan years 2021 through 2025 (section 1859(f)(8)(D)(ii) of the Act). In the April 2019 final rule (84 FR 15719 through 15720), we codified this enrollment sanction at § 422.752(d). From plan years 2021 through 2025, we used this sanction authority in numerous instances and found it helpful for States and new D-SNPs since it created a mechanism to suspend enrollment for D-SNPs when contracting with the State Medicaid agency is unexpectedly delayed. However, since the statutory authority for the enrollment sanction expires at the end of plan year 2025, we propose to remove § 422.752(d).

H. Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET (§ 423.2536)

Division CC, title I, subtitle B, section 118 of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260) amended section 1860D–14 of the Act by redesignating subsection (e) of section 1860D–14 of the Act as subsection (f) and by establishing a new subsection (e) Limited Income Newly Eligible Transition (LI NET) Program. Subsection (e)(1) directs the Secretary to carry out a program to provide transitional coverage for covered Part D drugs for LI NET eligible individuals no later than January 1, 2024. We published the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (88 FR 22342) in April 2023 establishing the LI NET program as a permanent part of Medicare Part D at 42 CFR part 423 subpart Y, beginning at § 423.2500.

Sections 1860D–14(e)(4) and (5) of the Act require that the program be administered through a contract with a single program administrator and exempts the LI NET program from certain beneficiary protection requirements for qualified prescription drug coverage under section 1860D–4 of the Act. Further, the Secretary may waive other such requirements of title XVIII of the Act as necessary to carry out the purpose of the program. Under our authority under section 1860D–14(e)(5)(B) of the Act, we propose to codify a waiver for the LI NET program with respect to customer call center

hours of operation for all regions served by LI NET.

Under § 423.128(d), a Part D sponsor is required to have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. Specifically, § 423.128(d)(1)(i)(A) requires that for coverage beginning on and after January 1, 2022, such mechanisms include a toll-free customer call center that is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan. Due to the nature of the LI NET program, maintaining a toll-free customer call center that is open Monday through Friday, except holidays, from 8:00 a.m. to 7:00 p.m. Eastern Time (ET) is sufficient because the customer call volume for LI NET after 7:00 p.m. ET has historically been low due to automatic enrollment of beneficiaries, the transitional nature of LI NET coverage, and LI NET's open formulary. The majority (for example, 90 to 95 percent) of LI NET beneficiaries are enrolled automatically by us and, as such, prospective enrollees rarely require customer call center assistance. Further, the requirement at § 423.128(d)(1)(i)(B) requires that any call center serving pharmacists or pharmacies be open so long as any network pharmacy in that region is open. Accordingly, these calls centers are available to address the majority of inquiries for the LI NET program and ensures that there is no impact on access. This proposal also aligns with the President's January 31, 2025, E.O., titled *Unleashing Prosperity Through Deregulation*, as we estimate that waiving the requirement for customer call center hours in all regions served by LI NET will save the program approximately \$800,000 to \$1,000,000 a year.

We propose to add the customer call center hours of operation for all regions served by the Part D plan in § 423.128(d)(1)(i)(A) to the list of Part D requirements waived for the LI NET program at § 423.2536.

We do not believe that the proposed changes to the regulatory text would adversely impact the LI NET sponsor, individuals' access to prescription drug benefits, the Medicare Trust Fund, or result in a paperwork burden.

VIII. Request for Information on Future Directions in Medicare Advantage (Risk Adjustment, Quality Bonus Payments, and Well-Being and Nutrition)

A. Introduction

The MA program has grown considerably in the past two decades and now covers over half of all

Medicare beneficiaries.¹⁰⁵ In light of this growth, CMS is interested in exploring opportunities for modernizing and strengthening the program, including with regard to payment, risk adjustment, and quality policy, with the aim of supporting competition and maximizing the value of the program for beneficiaries and taxpayers. Specifically, CMS believes that meaningful opportunities exist for enhancing the risk adjustment system and the quality bonus payment (QBP) program, consistent with findings from multiple studies by the Medicare Payment Advisory Commission (MedPAC)^{106 107} and other researchers.^{108 109 110} CMS is particularly interested in changes that can enhance competition in the MA program; level the playing field for smaller, regional, and less well-resourced MA plans; and address factors that may place these types of plans at a competitive disadvantage. Enhancements to competition in MA would be expected to yield substantial benefits for beneficiaries, taxpayers, health plans, and the Medicare program as a whole. For example, leveling the playing field in MA can translate into greater innovation in benefit design and care models, including greater use of high-value supplemental benefits, reduced use of low-value benefits and services, and improved health outcomes for beneficiaries.

CMS could pursue changes in MA through two possible channels. The first

is through rulemaking or other means authorized under law (e.g., the annual announcement of methodological changes to MA payment rates through the Advance Notice and Rate Announcement pursuant to section 1853(b) of the Act), which institute changes that are national in scale. The second channel is by testing a model under section 1115A of the Act through which the CMS Innovation Center can test innovative payment and service delivery models on either a regional or national scale. Section 1115A(c) of the Act authorizes the Secretary to expand the scope and duration of the tested model if such expansion is expected to reduce spending without reducing the quality of care or improve the quality of patient care without increasing spending; the Chief Actuary for CMS certifies the expansion would reduce or not increase program spending, and the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. If these requirements are met, the model can be expanded nationally to all relevant stakeholders in a mandatory fashion through rulemaking. Examples of expanded CMS Innovation Center models include the Diabetes Prevention Program,^{111 112} the Home Health Value-Based Purchasing Model,¹¹³ and Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT),¹¹⁴ which were found to reduce costs, improve quality, and reduce adverse medical events under Original Medicare. Throughout its history, the CMS Innovation Center has implemented only one MA-specific model, the Value-Based Insurance Design (VBID) model,¹¹⁵ which

¹⁰⁵ Medicare Payment Advisory Commission. (March 2025). "Report to the Congress: Medicare Payment Policy, Chapter 11, The Medicare Advantage Program: Status Report." https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch11_MedPAC_Report_To_Congress_SEC.pdf.

¹⁰⁶ Medicare Payment Advisory Commission. (March 2023). "Report to the Congress: Medicare Payment Policy, Chapter 11, The Medicare Advantage Program: Status Report." https://www.medpac.gov/wp-content/uploads/2023/03/Ch11_Mar23_MedPAC_Report_To_Congress_SEC.pdf.

¹⁰⁷ Medicare Payment Advisory Commission. (2024). "Report to the Congress: Medicare Payment Policy, Chapter 13, Estimating Medicare Advantage coding intensity and favorable selection." https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch13_MedPAC_Report_To_Congress_SEC.pdf.

¹⁰⁸ Kronick, R., & Chua, F.M. (2021). Industry-wide and sponsor-specific estimates of Medicare Advantage coding intensity. Available at SSRN 3959446.

¹⁰⁹ Markovitz, A.A., Ayanian, J.Z., Sukul, D., & Ryan, A. M. (2021). The Medicare Advantage Quality Bonus Program Has Not Improved Plan Quality: Study examines the impact of the Medicare Advantage quality bonus program. *Health Affairs*, 40(12), 1918–1925.

¹¹⁰ Layton, T.J., & Ryan, A.M. (2015). Higher incentive payments in Medicare advantage's pay-for-performance program did not improve quality but did increase plan offerings. *Health services research*, 50(6), 1810–1828.

¹¹¹ Centers for Medicare & Medicaid Services. Medicare Diabetes Prevention Program (MDPP): Expanded Model Fact Sheet. <https://www.cms.gov/files/document/mdpp-expansion-fact-sheet.pdf>.

¹¹² Centers for Medicare & Medicaid Services. (December 2024). Medicare Diabetes Prevention Program Expanded Model. <https://www.cms.gov/files/document/mln34893002-medicare-diabetes-prevention-program-expanded-model.pdf>.

¹¹³ Centers for Medicare & Medicaid Services. Home Health Value-Based Purchasing Model. <https://www.cms.gov/priorities/innovation/innovation-models/home-health-value-based-purchasing-model>.

¹¹⁴ Centers for Medicare & Medicaid Services. Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport. <https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives/prior-authorization-repetitive-scheduled-non-emergent-ambulance-transport-rsnat>.

¹¹⁵ Centers for Medicare & Medicaid Services. <https://www.cms.gov/priorities/innovation/innovation-models/vbid>.

terminates effective December 31, 2025.¹¹⁶ A CMS Innovation Center Model can be a channel for testing policy ideas that would benefit from testing, for example, if a policy has uncertain implications. The Innovation Center has the resources and flexibility to identify, develop, rapidly test and encourage voluntary, widespread adoption of innovative care and payment models. A CMS Innovation Center model is also an option for testing innovations that require the statutory authority of the Innovation Center model, for example, statutory waivers.

B. Risk Adjustment

1. Background

Risk adjustment shapes many aspects of the MA program. Risk adjustment constitutes a key part of the payment process and can influence the MA program in a number of direct as well as indirect ways. MA plan payments are calculated at an individual level to account for a beneficiary's expected health care costs, based on their specific demographic and health characteristics. Risk adjustment is accomplished through the calculation of the risk score, a number representing the ratio between a specific enrollee's predicted Original Medicare costs and average costs within Original Medicare. Ultimately, because risk adjustment has such an important role in payment policy, it can influence the types of enrollees that MA plans target for enrollment, how they market to enrollees, the types of supplemental benefits that plans offer, the prescription drugs that they cover, the providers they contract with, and the types of care that MA enrollees receive.¹¹⁷

Moreover, risk adjustment impacts competition between MA organizations and may impose inherent disadvantages on certain types of organizations over others.¹¹⁸ The existing risk adjustment model relies on medical diagnoses to predict health care costs, in addition to

demographic factors, which could lead plans to code more intensely than what is observed in Original Medicare. And while risk adjustment policies are intended to adequately compensate MA plans for their enrollees' expected costs, higher payments associated with higher risk scores may encourage MA organizations to prioritize investments in coding activities over care management or treatment.

To account for differences in coding patterns between MA and Original Medicare, section 1853(a)(1)(C)(ii) of the Act requires CMS to apply a coding adjustment factor each year when risk adjusting payments. In 2019 and subsequent years, the adjustment must be at least 5.9 percent. Nevertheless, the higher rates of coding in MA relative to Original Medicare may increase taxpayer expenditures and impose administrative burdens on plans, without any accompanying improvements to quality of care.¹¹⁹

CMS is, therefore, soliciting feedback on options for risk adjustment, including near-term changes to the existing risk adjustment methodology and entirely new approaches for risk adjustment, such as those that account for recent advances in technology. For example, CMS has previously contemplated including MA encounter data in the calibration of risk adjustment models, rather than solely relying on FFS data, to better capture patterns specific to the MA population. CMS seeks ideas for additional data sources and data elements for risk adjustment, and for how those data sources should best be incorporated, particularly to minimize opportunities for gaming by MA organizations, incentivize positive health outcomes, and minimize administrative burden for plans and providers. In particular, CMS seeks ideas for risk adjustment approaches that do not rely on collection of diagnoses data and, instead, incorporate alternative factors to infer a patient's health risk as well as the severity of that risk. Finally, CMS is interested in risk adjustment approaches that advance competition and foster a level playing field between different types of MA plans and MA organizations.

2. Solicitation of Comments

We are soliciting comments on opportunities for improving risk adjustment, inviting comments from a

broad range of stakeholders and interested parties, including MA organizations, beneficiary advocates, healthcare providers, and industry experts. We are particularly interested in comments on how to achieve the following goals with risk adjustment, relative to the current state:

- Advancing competition, removing anti-competitive barriers, and ensuring a level playing field for regional, smaller, and less well-resourced plans.
- Reducing manipulability of the risk adjustment system as well as the day-to-day administrative burden for both plans and providers.
- Ensuring accurate payments for sicker beneficiaries, while rewarding effective treatment and favorable patient outcomes.
- Mitigating unintended consequences and effectively navigating tradeoffs. (For example, how to approach a situation where a potential input to the risk adjustment model improves the predictive accuracy of the model but would also directly disincentivize valuable treatments for patients.)

- Incentivizing provision of tangible and high-value benefits and services and maximizing the value that beneficiaries, as well as taxpayers, get from payments to MA plans.

We are also soliciting more specific comments on potential methods for improving the MA risk adjustment program through the following questions:

- Which diagnoses are most essential for CMS to include in its MA risk adjustment model? In certain instances, should CMS limit the use of diagnoses in risk adjustment based on a minimum threshold of disease severity or to patient encounters within specific settings? Should CMS require diagnoses to be substantiated by follow-up encounters or treatments? Similarly, should CMS exclude diagnoses from plan-initiated encounters that do not lead to follow-up care, such as those resulting from in-home health risk assessments, or diagnoses not linked to specific services furnished to an enrollee?

- Over what timeframes should CMS incorporate diagnostic data for risk adjustment purposes? How can CMS account for certain illnesses and injuries that are likely to persist but may not be captured within a given data year by a patient encounter? Similarly, how should CMS account for past conditions that are no longer active, but continue appearing as diagnoses?

- When incorporating diagnostic data from particular encounters, should CMS account for the payment status of the

¹¹⁶ Centers for Medicare & Medicaid Services. (2024). Medicare Advantage Value-Based Insurance Design (VBID) Model to End after Calendar Year 2025: Excess Costs Associated with the Model Unable to be Addressed by Policy Changes. <https://www.cms.gov/blog/medicare-advantage-value-based-insurance-design-vbid-model-end-after-calendar-year-2025-excess-costs>.

¹¹⁷ Medicare Payment Advisory Commission. (June 2023). "Report to the Congress: Medicare Payment Policy, Chapter 4, The Medicare Advantage Program: Status Report." https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch4_MedPAC_Report_To_Congress_SEC.pdf.

¹¹⁸ Kronick, R., Chua, F.M., Krauss, R., Johnson, L., & Waldo, D. (2025). Insurer-Level Estimates of Revenue From Differential Coding in Medicare Advantage. *Annals of internal medicine*, 178(5), 655–662.

¹¹⁹ Medicare Payment Advisory Commission. (March 2025). "Report to the Congress: Medicare Payment Policy, Chapter 11, The Medicare Advantage Program: Status Report." https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch11_MedPAC_Report_To_Congress_SEC.pdf.

services associated with that encounter? For example, should the risk adjustment model include diagnoses from encounters where a payment was denied, or approved and later found to be improper?

- CMS has publicly discussed the prospect of moving towards a risk adjustment model calibrated based on encounter data. In addition to these efforts, should CMS consider testing new risk adjustment methods that replace the current Hierarchical Condition Category (HCC)-based risk adjustment model, such as an inferred risk adjustment model? How should CMS think about a model that is not primarily or solely based off medical diagnoses, but instead uses other types of information, such as utilization of medical services to infer both the presence and the severity of different conditions? What are alternative inputs that CMS should consider, which would be effective at predicting future health care spending by a patient, incentivizing appropriate care, while not being readily susceptible to gaming and manipulation? Likewise, how can a next generation risk adjustment model be structured to minimize unnecessary administrative burden for plans and providers, and structured to minimize the sensitivity of risk scores to administrative effort or administrative skill? How should a model be structured to best support competition and to ensure a level playing field for all MA plans?

- How might CMS utilize technological innovations, such as artificial intelligence (AI) and machine learning, in calibrating current or future risk adjustment methodologies? What are the benefits and risks of shifting from the existing linear regression methodology to one that utilizes AI and/or machine learning? Do plans have best practices when using AI? What types of protections need to be established to ensure the use of AI is fair? Can the efficiencies of AI be leveraged so as to reduce fraud, waste, and abuse?

- As part of either the existing HCC model or a next generation risk adjustment model, should CMS draw on additional elements within existing data sources, as well as entirely new sources of data? For example, should CMS incorporate prescription drug event data, beneficiary survey data, electronic medical record data, or lab data to infer an MA patient's expected health care spending and the severity of their medical conditions? What kinds of data elements should CMS draw on within existing data sources, specifically from medical claims and beneficiary characteristics files (for example,

procedure information)? Should CMS incorporate additional adjustments for a patient's place of residence to account for variation in costs within individual counties? How should CMS think about potential data sources that are not currently readily accessible or usable for the full population of Medicare beneficiaries, such as electronic medical record data? How should CMS go about making such novel data sources accessible and usable for risk adjustment, given that they would need to be accessible for every Medicare beneficiary?

- What other policy approaches should CMS consider to ensure that risk adjustment maximizes incentives for offering high-quality coverage rather than investment in coding practices that may not improve enrollee health?

In advance, we thank all commenters, as this feedback will help inform future CMS action in this area.

C. Quality Bonus Payments in Medicare Advantage

In this RFI, we solicit information from stakeholders and all interested parties to inform future policy development and potential refinement to the QBP structure for MA plans as authorized under section 1853(o) of the Act and the impact of QBPs on rebates as authorized under section 1854(b) of the Act.

The solicitation is meant to build upon information obtained from and issues that surfaced under past RFIs. For example, in the 2024 Consolidation in Health Care Markets RFI¹²⁰ jointly released by the Federal Trade Commission, the Department of Justice, and the Department of Health and Human Services, some respondents notably requested reforms to address potential gaming of risk and quality scores. Also, this solicitation is intended to address issues previously documented by MedPAC, academic researchers, and others, and in public comments on the annual Advance Notice of Methodological Changes for MA Capitation Rates and Part C and Part D Payment Policies (the Advance Notice).

It takes several years to test, validate, propose, and add a new measure to the Part C and Part D Star Ratings. Separately, for measures that are already implemented, a 2-year lag exists between the end of the measurement period and actual payment to the MA plan. CMS would like to explore

potential options to shorten the timeline for implementation of new measures, as well as the lag between measurement and payment for existing measures.

The regulations at 42 CFR 422.164(c)(2) and 42 CFR 423.184(c)(2) require CMS to announce potential new measures and solicit feedback through the Advance Notice and Rate Announcement process described in section 1853(b) of the Act and subsequently propose and finalize new measures through rulemaking. In addition, 42 CFR 422.164(c)(3) and 423.184(c)(3) require measures be on the display page on the CMS website for a minimum of 2 years while being finalized as Star Ratings measures used for payment. We, therefore, solicit comments on potential methods to condense the timeline to add a new measure to the Star Ratings, for example, by reducing the display period for new measures.

For existing measures, the lag between the Star Ratings measurement year and payment year is due to the statutory requirements at sections 1853(o) and 1854(b)(1)(C)(v)–(vi) of the Act, which link the MA bid process to QBP ratings. Since section 1854(a)(1)(A) of the Act requires that MA plans submit their bids not later than the first Monday in June prior to the start of the contract year (which is more than 6 months prior to the start of the contract year), and an MA plan's quality bonus amount impacts their bid submission, CMS uses the latest QBP ratings available as of that date. The QBP ratings thus employed as of the time of the bid involve a measure period from two calendar years prior, ultimately translating into up to a three-year overall lag between measurement and payment. Meanwhile, the time lag between the measurement and payment years creates a disconnect between the quality and financial reward, as MA plans receive bonuses based on their quality performance two years prior, which does not reflect any remediation since that time. To that effect, CMS is also soliciting information on whether CMS should test an Innovation Center model that would delink QBPs from MA bids, with the aim of further incentivizing health plans to improve quality and providing beneficiaries with more timely and actionable quality information. Specifically, CMS is soliciting comments on the following questions:

- What could an alternative policy look like, if one is needed at all?
- What are the potential advantages and disadvantages of the suggested alternative?

¹²⁰ Request for Information on Consolidation in Health Care Markets. (June 2024). <https://www.regulations.gov/docket/FTC-2024-0022/document>.

• When should bonus payments be finalized and disbursed? More broadly, how might CMS better incentivize cost containment within the MA program, while improving care quality?

D. Well-Being and Nutrition

The MA program offers a unique opportunity to bring high-value interventions designed to support overall well-being and nutrition to patients. To the extent that MA organizations are bearing financial risk related to the long-term health outcomes of the populations they serve, they will have an inherent incentive to support interventions that promote health over the long term by avoiding the high costs associated with chronic conditions.

We are seeking input on well-being policy changes for future years. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health while emphasizing preventative care to proactively address potential health issues.^[1] This comprehensive approach emphasizes person-centered care by promoting the well-being of patients and family members.

We are seeking comments on tools and policies that improve overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment. We would like to receive input and comments on the applicability of tools and constructs that assess for the integration of complementary and integrative health, skill building, and self-care. Please provide feedback on the relevant aspects of well-being for the MA program, with a particular emphasis on how incentives can be improved to ensure MA organizations are bearing long-term risk related to the health and well-being of their populations.

A second concept that we are seeking feedback on is for policy changes for nutrition. We are seeking comments on tools and policies that achieve optimal nutrition and improve preventive care in MA. Policies for nutrition improvement may include various

strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. Such policies may also include aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventive care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual's health and nutritional needs. We seek comment on the relevant aspects of optimal nutrition and preventive care for the MA program, with a particular emphasis on how incentives can be improved to ensure the risk borne by MA organizations provides them adequate incentive to support beneficiaries seeking to improve their nutritional habits.

While we will not be responding to specific comments in response to this RFI, we intend to use this input to inform our future policy development efforts.

IX. Technical Changes to Terminology in Risk Adjustment and in Payments to Sponsors of Retiree Prescription Drug Plans

We are proposing to update our regulations related to Medicare Advantage and the Medicare Prescription Drug Program to align with E.O. 14168—Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, issued on January 20, 2025. Per this E.O., we will replace the word “gender” with “sex” in §§ 422.308(c)(1) and 423.884(c)(2)(v)(D).

As these terms have no discernable operational difference in meaning with regard to risk adjustment and applications for qualified retiree prescription drug plans, there is no associated burden. Therefore, we have not included a discussion of this provision in the COI section of this rule.

We are not scoring this provision in the Regulatory Impact Analysis section because this technical change has no impact on program operations.

X. 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,” as defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule (CMS–4212–F, RIN 0938–AV63).

A. Wage Data

To derive average (mean) costs, we are using data from the most current U.S. Bureau of Labor Statistics’ (BLS’s) National Occupational Employment and Wage Estimates for all salary estimates (<https://www.bls.gov/oes/tables.htm>), which, at the time of publication of this proposed rule, provides May 2024 wages. In this regard, table J1 presents BLS’s 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 J1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupational Title	Occupational Code	Mean Hourly Wage (\$/hr)	Cost of Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Wage (\$/hr)
Business Operations Specialists, All Other	13-1199	44.41	44.41	88.82
Compensation and Benefits Managers	11-3111	75.11	75.11	150.22
Compliance Officers	13-1041	40.86	40.86	81.72
Computer Support Specialists	15-1230	32.47	32.47	64.94
Human Resources Managers	11-3121	77.15	77.15	154.30
Software Developers	15-1252	69.50	69.50	139.00

Adjusting our employee hourly wage estimates by a factor of 100 percent is a rough adjustment that is being used since 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. In this regard, we believe that doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this proposed rule.

1. ICRs Regarding Manufacturer Discount Program (§ 423.100 and §§ 423.2700–423.2768)

As described in section II.C. of this proposed rule, we are proposing to codify the policies established under the Manufacturer Discount Program Final Guidance,¹²¹ with certain refinements, as new subpart AA of part 423. Information collection requirements for the Manufacturer Discount Program are approved by OMB under control number 0938–1451 (CMS–10846). Codification of the Manufacturer Discount Program policies in this proposed rule would not impact the requirements or burden currently approved by OMB under this control number.

2. ICRs Regarding Special Enrollment Period for Provider Terminations (§ 422.62(b)(23))

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267). While the control number has expired, we are setting out this rule's collection of information requirements/burden to score the impact of such changes. We intend to use the standard PRA process (which includes the publication of 60- and 30-day non-rule

Federal Register notices) to reinstate the control number with change. The initial 60-day notice will publish sometime after the publication of this proposed rule.

As described in section IV.A. of this proposed rule, at § 422.62(b)(23) we propose to change the name and eligibility criteria for the current SEP for Significant Change in Provider Network to reflect that neither an MA organization determination nor a CMS determination of significant provider network change is necessary for an enrollee who is affected by the provider network change to be eligible for the SEP. We also propose that information regarding eligibility for the SEP be included in the provider termination notice. The requirement to issue a provider termination notice is described at § 422.111, where § 422.2267(e)(12) is referenced as the source for notice content requirements. Accordingly, we are proposing changes in the required content of the provider termination notice by revising § 422.2267(e)(12).

This proposal to amend § 422.2267(e)(12) would not impact MA organizations in terms of the burden required to identify those enrollees who must be notified of provider contract terminations per CMS requirements or to develop and send the required written notices. Instead, the impact of this provision arises from the one-time effort for MA organizations to update their existing written provider termination notice so it is in compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii)(D). We expect MA organizations to engage in some routine software development to update their notice template and related systems to incorporate the new proposed requirements, which we are proposing will be delineated in a provider termination model document developed by CMS. The proposed model will be posted for public review and comment in conjunction with this rule's proposed collection of information request under CMS–R–267.

We estimate it would take one or two software developers a total of 8 hours at \$139.00/hr to update their MA organization's existing provider termination notice template and related systems based on CMS's model. With approximately 697 MA organizations impacted by this proposed change, we estimate a total one-time burden of 5,576 hours (697 MA organizations * 8 hr) at a cost of \$775,064 (5,576 hr * \$139.00/hr).

Our proposal to amend the provider termination notice content requirements at § 422.2267(e)(12) would not affect the volume or frequency of provider contract terminations and, therefore, on its own, would not have the effect of increasing or decreasing the number of enrollees who must be notified of provider contract terminations. This proposed change would not impact the burden required of MA organizations to identify enrollees to whom notices must be sent and to send the required written notices.

3. ICRs Regarding Strengthened Documentation Standards for Part D Plan Sponsors

Under section 1860D–12(b)(3)(C) of the Act and § 423.505(d) and (e), Part D plan sponsors are required to maintain certain categories of documentation for specified periods of time. Specifically, § 423.505(d) requires that the contract between a Part D plan sponsor and CMS include an agreement by the Part D plan sponsor to maintain books, records, documents, and other evidence of accounting procedures and practices for 10 years that are sufficient to meet certain requirements, including enabling CMS to evaluate the quality, appropriateness, and timeliness of services performed under the contract and to audit the services performed or determinations of amounts payable under the contract. In addition, § 423.505(e) requires that Part D plan sponsors agree to HHS, the Comptroller General or their designee to evaluate through audit, inspection, or other means (1) the quality, appropriateness,

¹²¹ Available at: <https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf>.

and timeliness of those services furnished to Medicare enrollees; (2) compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees; (3) facilities of the Part D sponsor; and (4) enrollment/disenrollment records for the current contract period and 10 prior periods. Furthermore, §§ 423.568(a)(3), 423.570(c)(2), and 423.584(c)(1) outline requirements for Part D plan sponsors to establish and maintain a method of documenting and to retain documentation for oral requests for coverage determinations under standard timeframes, expedited timeframes, and redeterminations respectively.

In this proposed rule, CMS proposes to standardize the documentation requirements that plan sponsors must maintain, in regulation at § 423.505, to ensure that Part D plan sponsors provide CMS with all the information that the plan sponsors use for determining payment responsibility under the Part D benefit. CMS is proposing to standardize the documentation requirements because information currently obtained from and relied upon during coverage determinations, or point-of-sale (POS) edits, utilized to determine payment responsibility, are not always maintained in the necessary detail by the Part D plan sponsors to allow for CMS to evaluate if the PDE record was covered and paid under the Medicare Part D benefit in compliance with CMS policy(ies).

CMS proposes to modify § 423.505 to further clarify and set expectations on the specific type of information needed to support final payment determinations for coverage determinations, and POS edits to determine payment responsibility under the Part D benefit. We are proposing documentation requirements that include certain written, verbal, and electronic communications, such as the date and time the request was received; the name and title of the individual who submitted or verified the request; and the information used to make the coverage determination.

Based on the current regulations and plan sponsor expectations, CMS believes that this proposal is exempt from PRA requirements as such recordkeeping is a usual and customary business practice (5 CFR 1320.3(b)(2)). The ability of the plan sponsor to demonstrate their compliance with the rules and regulations of the Medicare Part D program is a basic requirement upon entering a contractual relationship with CMS. Plan sponsors are expected

to maintain documentation and produce that documentation upon request by CMS to evaluate the appropriateness of the services provided to the Medicare enrollee in accordance with the requirements at § 423.505. Based upon our past audit experience, plan sponsors maintain documentation to varying degrees and in some instances the documentation maintained is not sufficient for CMS to have confidence that the PDE record was covered and paid under the Part D benefit in accordance with CMS policy(ies). As such, CMS is proposing the documentation standards to allow CMS to perform the task of evaluating the appropriateness of the Medicare Part D coverage provided by plan sponsors for coverage determinations and POS edits that determine coverage. The documentation requirements must also be provided to CMS, in accordance with existing and proposed requirements at § 423.505 that allow CMS the right to evaluate and provide oversight of the program through audit. As such, we believe the proposed documentation standards that provide clarification of current expectations are exempt from any PRA.

4. ICRs Regarding Removing Rules on Time and Manner of Beneficiary Outreach (§§ 422.2264(c) and 423.2264(c))

The following proposed changes will be submitted to OMB for review under control number 0938–1442 (CMS–10837).

CMS is proposing three deregulatory changes to §§ 422.2264(c) and 423.2264(c) to remove rules on the time and manner of beneficiary outreach. These proposals are designed to improve the plan decision making process by creating a more convenient, beneficiary-friendly outreach experience and to reduce burden on beneficiaries, plans, and agents/brokers. The proposed deregulatory changes concern: (1) marketing events following educational events in the same location, (2) the timing of a personal marketing appointment after Scope of Appointment (SOA) form completion, and (3) SOA forms at educational events.

a. Marketing Events Following Educational Events in Same Location

For the proposed elimination of the requirement for a 12-hour delay between an educational and marketing event at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i), the information collection burden associated with this requirement is currently approved by OMB under the aforementioned control

number. This rule proposes to remove the one-time burden to change the MA organization's policies and procedures. With 697 contracts and 15 minutes (0.25 hr) per response at \$88.82/hr for a business operations specialist, we estimate a reduction of minus 174 hours (697 contracts × 0.25 hr) and minus \$15,477 (174 hr × \$88.82/hr).

b. Timing of Personal Marketing Appointment After Scope of Appointment (SOA) Form Completion

For the proposed elimination of the 48-hour waiting period required between the SOA completion and a personal marketing appointment at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i), the information collection burden associated with this requirement is currently approved by OMB under the aforementioned control number. This rule proposes to remove the one-time burden to change the MA organization's policies and procedures. With 697 contracts and 15 minutes (0.25 hr) per response at \$88.82/hr for a business operations specialist, we estimate a reduction of minus 174 hours (697 contracts × 0.25 hr) and minus \$15,477 (174 hr × \$88.82/hr).

c. Scope of Appointment (SOA) Forms at Educational Events

For the proposed elimination of the prohibition of the collection of SOA forms at educational events at §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D), the information collection burden associated with this requirement is currently approved by OMB under the aforementioned control number. This rule proposes to remove the one-time burden to change the MA organization's policies and procedures. With 697 contracts and 15 minutes (0.25 hr) per response at \$88.82/hr for a business operations specialist, we estimate a reduction of minus 174 hours (697 contracts × 0.25 hr) and minus \$15,477 (174 hr × \$88.82/hr).

5. ICRs Regarding Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits (Part 423 Subpart Z)

The effort associated with our proposed requirements under CITE consists of the time for plan sponsors to prepare and submit the appeal requests for: (1) reconsiderations, (2) hearing official review, and (3) review by the Administrator. However, the burden associated with the preparation and submission of appeals is exempt from the requirements of the PRA since such appeals would be submitted in response to an administrative action (5 CFR 1320.4(a)(2) and (c)).

We also believe that there would be no need for plan sponsors to establish a new appeals process or revise an existing appeals process.

6. ICRs Regarding Passive Enrollment by CMS (§ 422.60)

The proposed requirement and burden for D-SNPs will be submitted to OMB for review under control number 0938-TBD (CMS-XXXXX). At this time, the CMS number has yet to be assigned. Additionally, the OMB control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

In our April 2018 final rule, we finalized language authorizing CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D-SNP into another integrated D-SNP, after consulting with the State Medicaid agency that contracts with the D-SNP or other integrated managed care plan, when CMS determines that the passive enrollment will promote continuity of care and integrated care under § 422.60(g)(1)(iii). We also finalized, under § 422.60(g)(2), requirements an MA plan would have to meet to qualify to receive passive enrollments under paragraph (g)(1)(iii). However, in multiple situations where we have attempted to implement these requirements, we have encountered difficulty with receiving integrated D-SNPs meeting the portion of § 422.60(g)(2)(ii) requiring that receiving integrated D-SNPs have provider networks and facility networks that are substantially similar to the relinquishing integrated D-SNP. In our attempts to utilize passive enrollment, we found that while prospective receiving integrated D-SNPs had Medicare provider and facility networks that meet the MA network adequacy criteria at § 422.112, these networks were not substantially similar to the provider and facility networks in the relinquishing integrated D-SNPs.

We are proposing to amend § 422.60(g)(2)(ii) to require that the integrated D-SNP receiving passive enrollment provide a continuity of care to all incoming enrollees for 120 days. We believe that this extended continuity of care period would address the issue that we attempted to address at 83 FR 16504 in the April 2018 final rule, namely that the provider network comparability analysis would minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment.

In the April 2018 final rule (83 FR 16692), we estimated that approximately 1 percent of the 373 active D-SNPs offered at that time would meet the criteria and operate in a market where all of the conditions of passive enrollment are met and where CMS, in consultation with a State Medicaid agency, implements passive enrollment. We therefore estimated that there would be only four instances ($373 \text{ D-SNPs} \times 0.01$) in which CMS would conduct passive enrollment each year. Since we estimated fewer than 10 respondents, the information collection requirements and burden related to the final provisions under § 422.60(g) were exempt (5 CFR 1320.3(c)) from the requirements of the PRA. These estimates were accurate. In none of the years since § 422.60(g) has been in effect, have 10 or more D-SNPs met the criteria to participate in passive enrollment. We have no reason to believe that this will change.

For this rulemaking, we continue to estimate that approximately 1 percent of the projected 1,100 active D-SNPs expected for CY 2027 would meet the revised criteria and operate in a market where the conditions for passive enrollment are met and where CMS, in consultation with a State Medicaid agency, implements passive enrollment. We therefore estimate there would be 11 instances ($1,100 \text{ D-SNPs} \times 0.01$) in which CMS would conduct passive enrollment each year and the PRA requirements would apply. The actual number of D-SNPs eligible for passive enrollment primarily depends on State procurement decisions for affiliated Medicaid managed care contracts. Those State procurement calendars are not readily available. We welcome comments on our assumptions.

We believe that D-SNPs participating in passive enrollment, as proposed for amendment in this rulemaking, would require 40 hours at \$88.82/hr for a business operations specialist to make necessary policy and systems updates in preparation for participating in passive enrollment and 40 hours at \$64.94/hr for a computer support specialist. With 11 D-SNPs nationally participating in passive enrollment in any given year, we estimate a one-time burden of 880 hours ($11 \text{ D-SNPs} \times 80 \text{ hr}$) at a cost of \$67,654 [$(440 \text{ hr} \times \$88.82/\text{hr}) + (440 \text{ hr} \times \$64.94/\text{hr})$] to update policies and procedures, training materials, systems.

Per § 422.60(g)(4), D-SNPs approved by CMS to participate in passive enrollment are currently required to distribute two notices to individuals. The D-SNP must provide the first notice no fewer than 60 calendar days prior to the enrollment effective date and the

second notice no fewer than 30 days prior to the enrollment effective date. We believe a D-SNP business operation specialist would spend 20 hours at \$88.82/hr developing these notices. We estimate a one-time burden of 220 hours ($20 \text{ hr} \times 11 \text{ D-SNPs}$) at a cost of \$19,540 ($220 \text{ hr} \times \$88.82/\text{hr}$).

Based on July 2025 total D-SNP enrollment, we estimate 6,168,649 D-SNP enrollees or a CY 2025 average of 6,500 enrollees per D-SNP (6,168,649 D-SNP enrollees/949 D-SNPs). We are including this calculation to provide the average number of enrollees per D-SNP, which is used in calculations below.

We assume the following costs include paper, toner, envelopes, and postage (envelope weight is normally considered negligible when citing these rates and is not included) for hard-copy mailings:

- *Paper*: \$3.50 for a ream of 500 sheets. The cost for one page is \$0.007 ($\$3.50/500 \text{ sheets}$).
- *Toner*: \$70 for 10,000 pages. The toner cost per page is \$0.007 ($\$70/10,000 \text{ pages}$).
- *Envelope*: Bulk envelope costs are \$440 for 10,000 envelopes or \$0.044 per envelope.
- *Postage*: The cost of first-class metered mail is \$0.73 per letter up to 1 ounce. We estimate that a sheet of paper weighs 0.16 ounces ($10.0 \text{ lb}/1,000 \text{ sheets} \times 16 \text{ oz}/\text{lb}$), and do not anticipate additional postage for mailings in excess of 1 ounce.

We estimate the aggregate cost per mailed notice is \$0.802 [$(\$0.007 \text{ for paper} \times 2 \text{ pages}) + (\$0.007 \text{ for toner} \times 2 \text{ pages}) + \$0.73 \text{ for postage} + \$0.044 \text{ per envelope}$]. We assume a maximum of 2 double-sided pages (generally, weighing less than 1 ounce) will be needed for a passive enrollment notice. Because preparing and generating a hard-copy enrollment notice is automated once the systems have been developed, we do not estimate any labor costs. Therefore, we estimate a total annual mailing cost by sponsors to enrollees of \$114,686 ($6,500 \text{ enrollees} \times 2 \text{ mailings} \times 11 \text{ D-SNPs} \times \$0.802/\text{mailing}$).

7. ICRs Regarding Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D-SNP and Medicaid Fee-for-Service (§§ 422.107(d)(1) and 422.514(h))

The following proposed changes will be submitted to OMB for review under control number 0938-0753 (CMS-R-267). While the control number has expired, we are setting out this rule's collection of information requirements/burden to score the impact of such changes. We intend to use the standard PRA process (which includes the

publication of 60- and 30-day non-rule **Federal Register** notices) to reinstate the control number with change. The initial 60-day notice will publish sometime after the publication of this proposed rule.

We are proposing to amend §§ 422.107(d)(1) and 422.514(h) to allow D-SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D-SNP to continue enrollment of full-benefit dually eligible individuals in a D-SNP in the same service area where those individuals are enrolled in Medicaid FFS. As discussed in section VI.B. of this proposed rule, this proposed provision makes specific amendments to a finalized package of provisions from the April 2024 final rule, which limited enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and limited the number of D-SNP plan benefit packages an MA organization, its parent organization, or entity that shares a parent organization with the MA organization, could offer in the same service area as an affiliated Medicaid MCO. If finalized, our proposed provisions at §§ 422.107(d)(1) and 422.514(h) would create another exception to allow D-SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D-SNP to continue enrollment of full-benefit dually eligible individuals in a D-SNP in the same service area where those individuals are enrolled in Medicaid FFS.

In the information collection requirements in the April 2024 final rule (89 FR 30784), we stated that the provisions we finalized would create burden for MA organizations that offer multiple D-SNPs in a service area with a Medicaid MCO, noting that impacted MA organizations would need to non-renew or (more likely) combine plans and update systems as well as notify enrollees of plan changes. We also stated in the April 2024 final rule that we expected that MA organizations would need two software engineers with each working 4 hours at \$127.82/hr to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours at \$79.50/hr to update plan policies and procedures in the first year with no additional burden in future years. In aggregate, we estimated a one-time burden (for plan year 2027) of 600 hours (50 plans * 12 hr/plan) at a cost of \$67,028 (50 plans * [(8 hr * \$127.82/hr) + (4 hr * \$79.50/hr)]).

The modifications that we are proposing in section VI.B. of this proposed rule to §§ 422.107(d)(1) and

422.514(h) would allow D-SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D-SNP to continue enrollment of full-benefit dually eligible individuals in a D-SNP in the same service area where those individuals are enrolled in Medicaid FFS, and as such, would change which D-SNPs would be required to non-renew or combine plans, affecting the burden estimates finalized in the April 2024 final rule. Given the landscape of States that do not require mandatory Medicaid managed care for all of their full-benefit dually eligible individuals, we believe that based on our estimates, 15 MA organizations would be affected by this proposed exception. To account for the reduction in MA organizations affected by this proposed change to §§ 422.107(d)(1) and 422.514(h) as compared to the finalized burden estimates in the April 2024 final rule, we are reducing the previous burden calculation of 50 MA organizations by 15 MA organizations.

Because we believe that these proposed amendments to §§ 422.107(d)(1) and 422.514(h) would reduce the number of impacted MA organizations by 15 as compared to our finalized estimate in the April 2024 final rule, we are providing our estimate in the reduction of burden that would result if this proposal to amend §§ 422.107(d)(1) and 422.514(h) were to be finalized. The wage estimates in this notice of proposed rulemaking have been updated to reflect May 2024 BLS National Occupational Employment and Wage Estimates, where our estimates in the April 2024 final rule used BLS National Occupational Employment and Wage Estimates from May 2022.

We continue to expect that MA organizations would need two software engineers with each working 4 hours at \$139.00/hr to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours at \$88.82/hr to update plan policies and procedures in the first year with no additional burden in future years. In aggregate, we estimate a revised one-time burden (for plan year 2027) of 420 hours (35 plans * 12 hr/plan) at a cost of \$51,355 (35 plans * [(8 hr * \$139.00/hr) + (4 hr * \$88.82/hr)]).

In this regard, we estimate a burden reduced of minus 180 hours (420 hr – 600 hr) and minus \$15,673 (\$51,355 – \$67,028).

8. ICRs Removing Account-Based Medical Plans From Entities Required To Provide Creditable Coverage Disclosures

The following proposed changes will be submitted to OMB for review under control number 0938–1013 (CMS–10198).

As described in section VII.A. of this proposed rule, account-based plans, such as HRAs, including ICHRAs, are group health plans that are not, as section 1860D–13(b)(6)(B)(i) of the Act requires, entities that offer prescription drug coverage. Therefore, the benefit design of account-based plans makes concepts, such as disclosure of creditable coverage, inapplicable to those arrangements. This rule's proposal to exclude account-based plans from the group health plans that are required to disclose creditable coverage status to the Secretary and to Medicare-eligible individuals as required under § 423.56 will reduce private expenditures required to comply with federal regulations to provide creditable coverage disclosures, by avoiding duplicative efforts, and eliminating the need for these account-based plans to acquire additional resources and expertise to provide these disclosures.

The disclosure to the Secretary is required for certain entities listed at § 423.56(b) that are not excluded at § 423.56(e). The entities exempted under § 423.56(e) include PDPs, MA–PD plans, and PACE or cost-based HMOs or CMPs that provide “qualified Part D coverage” within the meaning of § 423.100. Among the plans that are required to submit this disclosure are group health plans (offered by employers, union/Taft-Hartley plans, church, State and local government, and other group-sponsored plans) including the Federal Employees Health Benefits Program; and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act. As described in section VII.A. of this proposed rule, the term, “Group Health Plan” (GHP) was codified at § 423.882 in the 2005 Part D final rule (70 FR 4577), and this definition includes account-based medical plans. The CMS online disclosure system allows entities to select the general type of GHP they offer (for example, employer-sponsored plans); however, the system does not provide for further subsets of the plan type. For example, account-based plans are not sub-categorized under the GHP category. Therefore, CMS does not have specific data on the number of account-based plans that may be making creditable coverage disclosures.

As stated in section VII.A. of this proposed rule, ICHRAs, a type of HRAs, are account-based plans that were more recently recognized by the Labor, Health and Human Services, and Treasury Departments in the June 20, 2019 final rule titled, “Health Reimbursement Arrangements and Other Account-Based Group Health Plans” (84 FR 28888). Generally, the impetus for this proposal to not require account-based plans to provide creditable coverage disclosures was feedback that CMS was receiving from stakeholders asking if ICHRAs were required to provide creditable coverage disclosures. To date, CMS has received minimal to no inquiries on the requirement for other types of account-based plans to make creditable coverage disclosures. Therefore, we will attempt to show a decrease in burden by comparing the number of ICHRA plans compared to the total universe of health plans, (about 5 percent), and inputting that percentage to estimate the number of ICHRA plans that are potentially making creditable coverage disclosures to the Secretary.¹²²

Using this data, we estimate that about 5 percent of the 140,974 GHPs, or

about 7,049 entities ($140,974 \times 0.05$) in our active burden estimates would not be required to make creditable coverage disclosures to the Secretary. Taking approximately 5 total minutes (0.083 hr) for either a Human Resources Manager at \$154.30/hr or a Compensation and Benefits Manager at \$150.22/hr (whichever individual/occupational title is assigned by the plan) to complete the online disclosure form, we estimate a reduction of minus 585 hours ($7,049 \times 0.083$ hr) and minus \$90,266 ($585 \times \$154.30/\text{hr}$ for a Human Resources Manager) or minus \$87,879 ($585 \times \$150.22/\text{hr}$ for a Compensation and Benefits Manager).

9. ICRs Regarding Rescinding the Annual Health Equity Analysis of Utilization Management (UM) Policies and Procedures (§ 422.137(c)(5), (d)(6), and (d)(7))

The following proposed changes will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

This rule proposes to remove § 422.137(c)(5), (d)(6), and (d)(7) which currently contain health equity reporting requirements related to UM. Rescission of these requirements would decrease the regulatory burden for MA organizations by removing reporting requirements for the UM Committee, reducing administrative complexity and eliminating ongoing compliance and monitoring. CMS proposes to remove the requirements since they impose compliance costs on MA organizations without corresponding benefits. The removal supports E.O.s 14148 and 14192 and addresses stakeholders’

concerns about the requirements’ lack of research foundation, feasibility, and administrative burden.

Section 422.137(c)(5) requires a member of the UM Committee to have expertise in health equity. CMS estimates it takes 30 minutes at \$81.72/hr for a compliance officer to update the policies and procedures. By removing this requirement, CMS estimates a one-time burden reduction of minus 348 hours ($697 \text{ contracts} \times 0.5 \text{ hr}$) and minus \$28,438 ($348 \text{ hr} \times \$81.72/\text{hr}$).

Section 422.137(d)(6) requires the UM Committee to conduct an annual health equity analysis of the use of prior authorization. CMS estimates it takes 8 hours at \$139.00/hr for a software developer to collect and aggregate the health equity analysis data required to produce the report. By removing this requirement, CMS estimates an annual burden reduction of minus 5,576 hours ($697 \text{ contracts} \times 8 \text{ hr/plan}$) and minus \$775,064 ($5,576 \text{ hr} \times \$139.00/\text{hr}$).

Finally, § 422.137(d)(7) requires that annually, the health equity analysis must be produced and posted to the plan’s website. CMS estimates it takes 10 minutes (0.1667 hr) at \$88.82/hr for a business operations specialist to produce, inspect, and post the report. By removing this requirement, CMS estimates an annual burden reduction of minus 116 hours ($697 \text{ contracts} \times 0.1667 \text{ hr/plan}$) and minus \$10,303 ($116 \text{ hr} \times \$88.82/\text{hr}$).

C. Summary of Proposed Information Collection Requirements and Associated Burden

BILLING CODE 4120–01–P

¹²² According to the 2024 KFF Employer Health Benefits Survey (available at <https://www.kff.org/health-costs/report/2024-employer-health-benefits-survey/>), of firms offering health benefits, 4 percent provide employees funds to purchase non-group coverage (such as through an ICHRA). Of firms not offering health benefits, 7 percent similarly provide employees funds to purchase non-group coverage (such as through an ICHRA). Based on these survey estimates, the weighted number of firms offering health benefits (1,670,244), and the estimated weighted number of firms not offering health benefits (1,589,106), it is estimated that there are 178,047 ICHRA plans in total. This is calculated as $(1,670,244 \times 0.04) + (1,589,106 \times 0.07) = 178,047$.

TABLE J5: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN

Regulatory Section in Title 42 of the CFR	Brief Description	OMB Control No. (CMS ID No.)	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost 1 st Year (\$)	Total Cost Subsequent Years (\$)
§ 422.62(b)(23)	Revise provider termination notice content requirements at 422.2267(c)(12)	0938-0753 (CMS-R-267)	697 MA organizations (contracts)	697	8	5,576	139.00	775,064	-
§§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i)	Removing Rules on Time and Manner of Beneficiary Outreach - Marketing Events Following Educational Events in Same Location	0938-1442 (CMS-10837)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	-
§§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i)	Removing Rules on Time and Manner of Beneficiary Outreach - Timing of Personal Marketing Appointment after Scope of Appointment (SOA) Form Completion	0938-1442 (CMS-10837)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	-
§§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D)	Removing Rules on Time and Manner of Beneficiary Outreach - Scope of Appointment (SOA) Forms at Educational Events	0938-1442 (CMS-10837)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	-
§ 422.60(g)	Passive Enrollment (plan burden)	0938-TBD	11 D-SNP (contracts)	11	100	1,100	79.27	87,195	87,195
§ 422.60(g)	Passive Enrollment (mailing costs)	0938-TBD	11 D-SNP (contracts)	11	N/A	N/A	N/A	114,686	114,686
§§ 422.107 and 422.514	Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D-SNP and Medicaid Fee-for-Service	0938-0753 (CMS-R-267)	15 MA organizations (contracts)	(15)	12	(180)	122.27	(15,673)	-
§ 423.56(b)(3)	Removing Account-based Medical Plans from Entities Required to Provide Creditable Coverage Disclosures	0938-1013 (CMS-10198)	7,049 Group Health Plans	(7,049)	0.083	(585)	154.30	(90,266)	(90,266)
§§ 422.137(c)(5), (d)(6) and (d)(7)	Rescinding the Annual Health Equity Analysis of UM Policies and Procedures	0938-0964 (CMS 10141)	697 MA organizations (contracts)	(697)	8.667	(6,040)	103.18	(813,805)	(785,367)
Total				(9,133)	Varies	(651)	Varies	10,770	(673,752)

BILLING CODE 4120-01-C

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit CMS' PRA website at <https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing> or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the DATES and ADDRESSES sections of this proposed rule and identify the rule (CMS-4212-P), the ICR's CFR citation, and OMB control number.

XI. Regulatory Impact Analysis*A. Statement of Need*

This proposed rule addresses several critical needs in the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), and Medicare cost plan that require regulatory action to ensure program integrity, beneficiary protection, and statutory compliance. The provisions proposed in this rule are intended to codify and implement the statutory requirements of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169), and provide greater clarity on the Star Ratings system for plans operating in the MA and Part D spaces.

One of the primary drivers for this rulemaking is the statutory mandate to implement changes made by the IRA. The IRA fundamentally restructured the Part D benefit design and established new payment obligations for enrollees, Part D plan sponsors, pharmaceutical manufacturers, and CMS. Without regulatory implementation of these statutory changes, the Medicare program cannot comply with Federal law or provide the intended beneficiary

protections and cost savings envisioned by Congress. Specifically, the IRA requires CMS to codify changes to Part D benefit phases, including the deductible, initial coverage limit, coverage gap, and the annual out-of-pocket threshold, as well as to sunset the Coverage Gap Discount Program and to establish the Medicare Part D Manufacturer Discount Program.

The proposed changes to Star Ratings address the ongoing need to simplify and refocus quality measurement, improving transparency for MA organizations and Part D sponsors. The current Star Ratings system has grown in complexity over time, and stakeholders have requested streamlining to focus on the most impactful quality measures. The proposed modifications respond to these requests and should make the Star Ratings system more comprehensible and predictable.

The absence of regulatory action would result in statutory non-compliance regarding IRA implementation, ongoing operational inefficiencies, and missed opportunities for program improvement and innovation. Therefore, this rulemaking is necessary to ensure the Medicare program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries.

B. Overall Impact Analysis

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993); Executive Order 13132, "Federalism"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96-354); section 1102(b) of the Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

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, and distributive impacts). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more, or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OIRA has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866.

C. Detailed Economic Analysis

Many provisions of this proposed rule have negligible impact either because they are technical provisions or clarifications. Throughout the preamble we have noted when we estimated that provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions' effects are estimated in section X. of this proposed rule, which estimates costs associated with paperwork burden resulting from this rule. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this RIA cross-references impacts from section X. of this proposed rule in order to arrive at the total impact. Table K1 summarizes the estimated transfers and costs associated with the various provisions in this proposed rule over a 10-year period. Further details are provided later in this RIA.

BILLING CODE 4120-01-P

TABLE K1: SUMMARY OF THE TRANSFERS AND COSTS OF THE PROPOSED RULE BY PROVISION FOR YEARS 2026-2036 (In \$ Millions)

Category of Provisions	Year(s)											
	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2026-2036
Transfers												
Star Ratings	-	-	5,020	2,320	780	700	730	840	940	900	950	13,180
Continuity in Enrollment for Full-Benefit Dually Eligible Individuals	-	-	-	-	5	5	5	5	7	7	7	41
TOTAL TRANSFERS	-	-	5,020	2,320	785	705	735	845	947	907	957	13,221
From the Medicare Trust Funds to MA Organizations and Part D Sponsors												
COSTS*	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2026-2036
TPMO Oversight: Revising the Record Retention Requirements for Marketing and Sales Call Recordings	-	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-67.2
Rescinding the Mid-Year Supplemental Benefits Notice	-1.9	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-15.4
Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET	-	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-10
Other Provisions†	-	-	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-6.1
TOTAL COSTS	-1.9	-9.1	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-98.7

* Figures in the Costs section of Table K1 have been rounded to the nearest tenth of one million. For that reason, numbers in the 2026-2036 column may not equal the sum of columns 2026 through 2036.

†The Other Provisions row includes estimates for first year and annually recurring impacts for the Information Collection Requirements of the following provisions: Special Enrollment Period for Provider Terminations; Removing Rules on Time and Manner of Beneficiary Outreach; Passive Enrollment; Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D-SNP and Medicaid Fee-for-Service; Removing Account-based Medical Plans from Entities Required to Provide Creditable Coverage Disclosures; and Rescinding the Annual Health Equity Analysis of Utilization Management Policies and Procedures.

BILLING CODE 4120-01-C

1. Effects of Part D Redesign: Redesigned Part D Benefit

In this proposed rule, we are proposing to codify changes to the Part D benefit made by section 11201 of the IRA related to the deductible, initial coverage limit, the coverage gap, the annual out-of-pocket (OOP) threshold, and alternative prescription drug coverage options. Several of the changes made by section 11201 have taken effect already and other changes will go into effect in 2026.

The Part D defined standard benefit becomes richer because of these changes, providing Part D enrollees with more protection from prescription drug costs. As Part D plan offerings must satisfy equivalence testing with the new, more generous benefit structure, they must also cover a greater share of Part D drug costs. This leads to higher bids and increases in federal costs for the program. In particular, the creation of an out-of-pocket maximum shields enrollees entirely from cost sharing once they enter the catastrophic phase of the benefit, leading to cost increases for Part D plans and the government. The costs and transfers attributable to the Part D redesign are attributable to the IRA and are not a result of this rule.

2. Effects of Part D Redesign: Specialty Tier

a. Limit on Specialty-Tier Cost Threshold Adjustment (§ 423.104(d)(2)(iv)(B))

In this proposed rule, we are proposing to revise § 423.104(d)(2)(iv)(B)(1) and (2) to allow CMS to reduce the specialty-tier cost threshold under certain circumstances, in addition to the current authority to increase the threshold. This change would provide CMS with additional flexibility to reduce the threshold in response to market conditions, such as potential reductions in Part D drug costs resulting from the Medicare Drug Price Negotiation Program.

This provision does not impose new requirements on Part D sponsors or change existing operational processes. The methodology for determining whether a threshold adjustment is warranted remains the same (at least 10 percent change from the prior year), and the rounding methodology remains unchanged. Therefore, we do not anticipate that this provision will have a measurable economic impact on Part D sponsors, beneficiaries, or the Medicare program, as it is only providing CMS with flexibility in making threshold adjustments without

altering the underlying methodology or operational requirements.

b. Specialty-Tier Maximum Allowable Cost Sharing (§ 423.104(d)(2)(iv)(D))

We are proposing to codify the methodology for determining the specialty-tier coinsurance/deductible ranges that were established in the Final CY 2025 Part D Redesign Program Instructions. This proposal would update the existing calculation methodology to align with the redesigned Part D benefit structure implemented under the IRA, which eliminated the initial coverage limit.

The proposed methodology maintains the existing 25 percent minimum and 33 percent maximum coinsurance for specialty tiers. While the underlying calculation has been updated to reflect the redesigned Part D benefit, the range of allowable coinsurance percentages remains unchanged. Part D sponsors must continue to ensure their benefit designs are actuarially equivalent to the defined standard benefit, as required under existing regulations.

When CMS codified the specialty-tier maximum allowable cost-sharing methodology in the CY 2022 Final Rule (86 FR 6078), we concluded in the regulatory impact analysis that the specialty-tier provisions, which also included provisions to allow Part D sponsors to structure their benefits with a second, “preferred” specialty tier, were unlikely to have a material impact on Part D costs. Likewise, we do not anticipate that our current proposal to update this methodology to align with the redesigned Part D benefit would have a measurable economic impact on Part D sponsors, beneficiaries, or the Medicare program, as it maintains the same coinsurance ranges that are currently in effect.

3. Effects of the Medicare Coverage Gap Discount Program (§§ 423.100, and 423.2300 Through 423.2345 (Subpart W))

This proposal would codify the sunset of the Coverage Gap Discount Program, which was enacted under the Affordable Care Act and began on January 1, 2011. The Coverage Gap Discount Program sunset was authorized as a part of the Part D benefit redesign under section 11201 of the IRA. Section 11201 of the IRA amended section 1860D–14A of the Act by adding subsection (h) to require that Coverage Gap Discount Program provisions at section 1860D–14A apply before January 1, 2025, and, with respect to applicable drugs dispensed prior to such date, continue to apply on and after January 1, 2025.

The costs and transfers attributable to the Part D Redesign, including sunseting the Coverage Gap Discount Program, are attributable to the IRA and are not a result of this rule.

4. Effects of the Medicare Part D Manufacturer Discount Program (§§ 423.1, 423.100, 423.505(b), 423.1000, 423.1002, and 423.2700 Through 423.2768 (Subpart AA))

This proposal would codify policies implementing the Manufacturer Discount Program. Section 11201 of the IRA established the Manufacturer Discount Program as a part of the IRA’s Part D benefit redesign. Section 11201(f) of the IRA directed CMS to implement the Manufacturer Discount Program using program instruction or other forms of program guidance for 2025 and 2026. The Manufacturer Discount Program began on January 1, 2025, and we are proposing to codify the policies that have been in place since the program’s implementation, with refinements.

The costs and transfers attributable to the Part D Redesign, including codifying the Manufacturer Discount Program, are attributable to the IRA and are not a result of this rule.

5. Effects of Third-Party Marketing Organization (TPMO) Oversight: Revising the Record Retention Requirements for Marketing and Sales Call Recordings

This provision proposes to reduce the amount of time that MA Organizations and Part D sponsors are required to retain recordings for sales and marketing calls from 10 to 6 years that was originally established in the May 2022 final rule (87 FR 27704) and subsequently modified in the April 2023 final rule (88 FR 22120) which required an MA organization or a Part D sponsor’s contract, written arrangement and/or agreement with the aforementioned entities must ensure that marketing, sales, and enrollment calls with beneficiaries are recorded in their entirety. In addition, CMS has advised that marketing, sales, and enrollment call recordings must comply with the record retention requirements at §§ 422.504(d) and 423.505(d). If finalized, the reduced call retention time from 10 to 6 years will take effect on October 1, 2026, to coincide with the beginning of 2027 plan year marketing, as defined under §§ 422.2263(a) and 423.2263(a).

To determine the cost of the existing requirement and thus the cost savings, CMS reviewed different types of storage costs. The first type is storage in cloud settings where an entity pays per

gigabyte or terabyte and the cost is determined based on the amount of data and how accessible the entity wants the data to be (for example, standard storage, cold line storage, archive storage, etc.). CMS also reviewed other options available for TPMOs, especially individual agents or small agencies, to record and store calls. In this review, CMS found that the industry created and/or marketed different recording tools available to agents and brokers. These tools have a wide range of costs, ranging from free recording services to other tools that are structured around monthly or yearly fees. Moreover, based on information gleaned from previous regulatory work, CMS has also been made aware that field marketing organizations (FMOs) may provide agents and brokers access to call recording technology at a reduced cost or otherwise factor it into agent/broker contractual arrangements. Finally, CMS notes that many of these tools are proprietary and total costs may not be fully transparent until a purchase (or contractual agreement) is made. All told, the variability makes it more difficult to establish the savings associated with this provision.

To estimate the cost savings associated with revising the call recording retention requirement, CMS first estimated the number of licensed and appointed agents to sell Medicare products, including MA plans and PDPs, to be 100,000.¹²³ CMS acknowledges that there is a range of how each agent accesses call recordings and storage and how much each will pay for these features. CMS also acknowledges that the typical cost to agents combines both the recording and the storage costs into one fee. With these challenges acknowledged, for this proposed rule, CMS is using an average cost of \$35 per month, or \$420 per year for call recording tools based on the median of the costs that agency was able to identify.^{124 125 126 127} Further, CMS is estimating that approximately 60% of the cost is attributed to the recording costs while the other 40% is attributed to the cost of storage (\$14 is storage [35×0.4]). Since the proposal requires calls to be retained for 6 years there would be a savings of \$5.6 per month

($\$14 \times 0.4$), resulting in a savings of \$67.2 per year per agent. Using the \$67.2 per year, combined with the estimated 100,000 agents and brokers licensed and appointed to sell Medicare products, CMS estimates that this provision will save an estimated \$6.72 million dollars per year ($\$67.2$ [savings per agent per year] * 100,000 [agents]), or 67.2 million dollars over a 10-year period.

Based on the previous noted limitations, CMS is specifically requesting comments on these estimates and welcomes additional data that may help the agency to further quantify the savings associated with this provision. We request comments on our assumptions of savings, taking into account the continued requirement for the recording of a beneficiary's enrollment into a plan.

6. Effects of Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.164, 422.166, 423.184, and 423.186)

We are proposing to add and remove certain measures from the Part C and D Star Ratings program. Historically, measure additions and removals are routine, and such routine changes have had very little or no impact on the highest ratings (that is, overall rating for MA-PD contracts, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). However, given the number of measure removals proposed in this rule, we have estimated the impact of the measure removals on the Medicare Trust Fund in this rule. We are also proposing to not move forward with the implementation of the Health Equity Index (HEI) reward and to continue to include the historical reward factor in the Star Ratings methodology. Beyond the Medicare Trust Fund, there may be effects on supplemental benefits, premiums, and plan profits. These impacts will likely vary significantly from plan to plan (or contract to contract) based on the business strategies and the competitive landscape for each plan and contract.

We simulated the cumulative impact of the proposed changes on MA contracts using the 2025 Star Ratings data. We calculated the net impacts summarized in Table K–3 due to these proposed Star Ratings updates by quantifying the difference in the MA organization's final Star Rating with the proposed changes and without the proposed changes. We assume Medicare Trust Fund impacts due to the Star Ratings changes associated with these proposed revisions to the measure set and methodology. Not moving forward with the implementation of the HEI and continuing to include the historical

reward factor would be effective for the 2027 Star Ratings and would impact the 2028 plan payments and 2028 Quality Bonus Payments (QBPs). The removal of the Call Center—Foreign Language Interpreter and TTY Availability (Part C), Call Center—Foreign Language Interpreter and TTY Availability (Part D), and Statin Therapy for Patients with Cardiovascular Disease (Part C) measures would be effective also for the 2028 Star Ratings and would impact the 2029 plan payments and 2029 QBPs. The removal of the remaining measures would be effective for the 2029 Star Ratings and would impact the 2030 plan payments and 2030 QBPs.

All impacts are considered transfers, but we request comments on the extent to which provision of goods or services would increase or decrease in association with the payment changes. The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those MA contracts that would have Star Ratings changes under this proposed rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

- A Star Rating of 4.0 or higher will result in a QBP for the MA contract, which, in turn, leads to a higher benchmark for the MA plans offered by the MA organization under that contract. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).
- The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, baseline assumptions are updated with the assumed Star Ratings changes described in this proposed rule. We estimated the cumulative impact of the proposed changes to the Star Ratings calculations since there are interactions between the changes. The impacts are shown in Table K3. For the Star Ratings updates, the net impact is estimated to be between \$5.02 billion in 2028 and \$0.95 billion in 2036, resulting in a 10-year net impact estimate of \$13.18 billion, which equates to 0.15 percent of the Medicare payments to private health plans for the years 2027 through 2036.

¹²³ <https://www.sparkadvisors.com/resource/where-agents-become-pawns-the-dark-side-of-fmo-contracting-and-what-it-means-for-agents>.

¹²⁴ <https://www.claap.io/blog/chorus-pricing>.

¹²⁵ https://www.nextiva.com/x20/lpGVDt11?utm_source=getvoip&utm_medium=affiliate&utm_campaign=lpGVDt&utm_term=nextiva%20plans.

¹²⁶ <https://www.zoom.us/pricing/zoom-phone>.

¹²⁷ CMS recognizes that some of the tools do not include unlimited, 10-year storage. Storage may be an additional cost.

TABLE K3: NET IMPACTS (\$ MILLIONS) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Net Impact Star Ratings Updates	Percent of Medicare Payments to Private Health Plans
2027	-	0.00%
2028	5,020	0.80%
2029	2,320	0.33%
2030	780	0.10%
2031	700	0.08%
2032	730	0.08%
2033	840	0.09%
2034	940	0.09%
2035	900	0.08%
2036	950	0.08%
Total	13,180	0.15%

7. Effects of Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D-SNP and Medicaid Fee-for-Service (§§ 422.107 and 422.514)

In the April 2024 final rule, we finalized a package of provisions at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h) that require that, beginning in contract year 2027, where an MA organization offers a D-SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service areas (even if there is only partial overlap of the service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dual eligible individuals, except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D-SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO. Per § 422.514(h)(2), beginning in contract year 2030, such D-SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO, except that such D-SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d). We also codified at § 422.514(h)(3) two exceptions to the requirements at § 422.514(h)(1) and (2) for exceptions related to instances where (a) the State

Medicaid agency contract (SMAC) with the MA organization differentiates enrollment into D-SNPs by age group or to align enrollment in the D-SNP with the eligibility or benefit design used in the State's Medicaid managed care program and (b) the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D-SNPs and PPO D-SNPs.

In the April 2024 final rule at 89 FR 30802 through 30805, we stated that our changes would yield an overall annual estimate of net Part C costs ranging from – \$6 million in contract year 2027 to – \$207 million in contract year 2034 with total net Part C costs of – \$961 million from contract years 2027 through 2034. We estimated an overall annual estimate of net Part D costs would range from – \$7 million in contract year 2027 to – \$286 million in contract year 2034 with total net Part D costs of – \$1,341 million from contract years 2027 through 2034. In the April 2024 final rule (89 FR 30803), we explained that the regulatory change would shift enrollment from less integrated D-SNPs to more integrated D-SNPs over time as more D-SNPs align with Medicaid MCOs. For more context regarding the estimation methodology, see the April 2024 final rule (89 FR 30802 through 30805).

In this proposed rule, we are proposing to add a third exception at § 422.514(h)(3) to allow D-SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D-SNP to continue

enrollment of full-benefit dually eligible individuals in a D-SNP in the same service area where those individuals are enrolled in Medicaid FFS. These proposed changes would address the challenges of MA organizations complying with the requirements at § 422.514(h) in States where there is no mandatory Medicaid managed care program and avoid the need for MA organizations in those States to cease enrolling full-benefit dually eligible individuals who are in Medicaid FFS starting in 2027 and disenroll those members in 2030 as currently required under § 422.514(h).

We expect that our proposal to establish a third exception at § 422.514(h)(3) would slightly reduce the savings estimates included in the April 2024 final rule since the number of D-SNPs and enrollees impacted by the existing requirement at § 422.514(h) would be reduced, should our proposal be finalized. We note that we are also proposing to add a fourth exception at § 422.514(h)(3) to exempt U.S. Territories that have not adopted Medicare Savings Programs (as defined at § 435.4) from the requirements at § 422.514(h)(1)(i), but we do not expect that this exception would have an impact on savings estimates in the April 2024 final rule. The methodologies and baseline data used in the estimates presented in Table K4 are consistent with those used in the April 2024 final rule estimates, except the Tables K4 and K5 estimates exclude certain HIDE SNPs and coordination-only D-SNPs that

would be exempt under this proposed rule.
For our proposed change to add a third exception at § 422.514(h)(3), as shown in Table K4, we estimate the Part

C costs to the Medicare Trust Funds range from \$0 million in 2027 to \$3 million in 2036, summing to \$18 million for the years 2027 through 2036. These estimated costs mean our overall

expected Part C savings from implementation of § 422.514(h) would be \$943 million (rather than \$961 million) over 10 years.

TABLE K4: ESTIMATED PART C COSTS (SAVINGS) PER YEAR (\$ MILLIONS) TO THE MEDICARE TRUST FUND FOR EXEMPTING CERTAIN D-SNP ENROLLMENT FROM § 422.514(h)

Calendar Year	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
BID + REBATE PMPM Difference in Dollars	13.10	13.16	13.02	12.89	12.93	13.04	13.92	14.51	15.10	15.67	
PROJECTED D-SNP Enrollment Exempt from 422.514(h)	517	1,015	1,489	16,228	16,609	16,942	17,239	17,496	17,721	17,904	
Gross Cost (\$ millions):	0	0	0	3	3	3	3	3	3	3	21
Net of Part B Premium:	85.1%	85.0%	84.9%	84.8%	84.8%	84.7%	84.7%	84.6%	84.6%	84.6%	
Net Cost (\$ millions):	0	0	0	2	2	2	2	3	3	3	18

Table K5 shows the estimated Part D costs of the proposed amendment to § 422.514(h) range from \$0 million in 2027 to \$4 million in 2036, summing to

\$24 million for the years 2027 through 2036. These estimated costs mean our overall expected Part D savings from implementation of § 422.514(h) would

be \$1,317 million (rather than \$1,341 million) over 10 years.

TABLE K5: ESTIMATED PART D COSTS (SAVINGS) PER YEAR (\$ MILLIONS) TO THE MEDICARE TRUST FUND FOR EXEMPTING CERTAIN D-SNP ENROLLMENT FROM § 422.514(h)

Calendar Year	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
BID + REINSURANCE PMPM Difference in Dollars	14.09	14.25	14.67	15.00	15.30	15.87	16.47	16.97	17.49	18.03	
Gross Cost (\$ millions):	0	0	0	3	3	3	3	4	4	4	24
Net Part D Premium:	-	-	-	-	-	-	-	-	-	-	-
Net Cost (\$ millions):	0	0	0	3	3	3	3	4	4	4	24

8. Effects of Rescinding the Mid-Year Supplemental Benefits Notice

This provision proposes rescinding the requirement established in the April 2024 final rule (89 FR 30448) that will require MA organizations to provide annual mid-year notices to enrollees regarding unused supplemental benefits. The requirement will take effect on January 1, 2026, and requires MA organizations to mail a notice between June 30 and July 31 of each plan year to enrollees listing any supplemental benefits they had not utilized during the first 6 months of the plan year. Note that on September 8, 2025, CMS announced its decision to delay enforcement of the requirements under §§ 422.111(l) and 422.2267(e)(42) until further notice. MA organizations are not expected to complete the Mid-Year Supplemental Benefits Notice requirements for the 2026 plan year.

a. Information Collection Requirements

In anticipation of this rescission, CMS removed the associated information collection requirements from PRA package CMS R-267 prior to its submission to OMB for review. Therefore, there are no current

information collection requirements associated with this provision that require OMB review or approval for rescission.

The rescission of this requirement would prevent the burden that would have been imposed on MA organizations. Based on updated BLS wage data, this would prevent approximately \$498,522 in one-time costs for system updates and policy changes, and approximately \$1,355,520 annually in printing and mailing costs.

b. Updated One-Time Cost Prevention

The rescission of this requirement would prevent approximately \$499,091 in one-time costs for system updates and policy changes across 774 prepaid contracts. This includes \$430,344 (774 prepaid contracts * 4 hours * \$139.00/hour) for software system updates performed by software developers, and \$68,746.68 (774 prepaid contracts * 1 hour * \$88.82/hour) for policy and procedure updates performed by business operations specialists.

c. Annual Cost Prevention

The rescission of this requirement would prevent approximately \$1,355,520 per year in printing and

mailing costs across 774 prepaid contracts serving 32 million enrollees. This includes \$451,840 (32,000,000 notices × \$0.01412/page) for single-page mailings, with an estimated average of 3 pages per enrollee resulting in total annual cost prevention of \$1,355,520 (32,000,000 notices × 3 pages × \$0.01412/page).

Over a 10-year period from 2027 to 2036, we estimate this provision would save approximately \$14.1 million (approximately \$1.4 million per year), primarily from the elimination of printing and mailing costs that would have been incurred annually, plus the one-time system and policy update costs prevented.

This proposed rescission is consistent with E.O. 14192, “Unleashing Prosperity through Deregulation,” which instructs federal agencies to review regulations to alleviate unnecessary regulatory burdens. After reviewing stakeholder feedback and current data on supplemental benefit utilization, CMS determined that the Mid-Year Notice requirement imposes a significant administrative burden on MA organizations that outweighs the intended benefit. Additionally, recent

evidence suggests that enrollees are utilizing supplemental benefits when they need them, with 70 percent of MA enrollees in a recent survey reporting they had used at least one supplemental benefit in the past year.

9. Effects of Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET

This provision adds a new waiver to the list of Part D requirements waived for the LI NET program by exempting the customer call center hours of operation requirements in § 423.128(d)(1)(i)(A). Currently, Part D sponsors are required to maintain toll-free customer call centers open from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan. This waiver allows the LI NET program to operate its customer call center Monday through Friday, except holidays, from 8:00 a.m. to 7:00 p.m. Eastern Time.

We estimate that this waiver will result in cost savings of approximately \$800,000 to \$1,000,000 annually for the LI NET program. These savings result from reduced operational costs associated with maintaining extended customer call center hours.

The reduced hours are appropriate for the LI NET program due to several factors: low call volume after 7:00 p.m. ET historically; automatic enrollment of 90 to 95 percent of LI NET beneficiaries by CMS, reducing the need for prospective enrollee assistance; the transitional nature of the LI NET program; LI NET's open formulary structure; availability of a 24-hour call center serving pharmacists and pharmacies to address the majority of inquiries.

This provision would not adversely impact the LI NET sponsor, individuals' access to prescription drug benefits, or the Medicare Trust Fund. The 24-hour pharmacy call center ensures continued access to necessary support, while the reduced customer call center hours align with actual usage patterns.

D. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this proposed rule would, if finalized, codify existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification existing policy would not affect compliance. In

such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health.

1. Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET (§ 423.2536)

The first alternative we considered would maintain the current customer call center hours requirement. The LI NET program would comply with the existing customer call center hours requirement in § 423.128(d)(1)(i)(A), maintaining operations from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan. This alternative would result in continued operational costs of approximately \$800,000 to \$1,000,000 annually compared to the proposed waiver. We reject this alternative because maintaining extended hours is not cost-effective given the historically low call volume after 7:00 p.m. ET. The automatic enrollment process for 90 to 95 percent of LI NET beneficiaries significantly reduces customer service needs, making the extended hours unnecessary. The continued availability of 24-hour pharmacy support ensures adequate access to assistance.

The second alternative we considered would eliminate the customer call center requirements for LI NET. The LI NET program would be completely exempt from maintaining any customer call center, relying solely on the 24-hour pharmacy call center. This alternative would result in maximum cost savings but could potentially impact beneficiary access to customer service. We reject this alternative because it could create access barriers for the 5 to 10 percent of LI NET beneficiaries who are not automatically enrolled and may need customer service assistance. Maintaining customer call center operations during standard business hours (8:00 a.m. to 7:00 p.m. ET) provides an appropriate balance between cost efficiency and beneficiary access to support services.

The proposed provision represents the optimal balance between operational efficiency and beneficiary protection, providing necessary customer service access while eliminating unnecessary costs associated with low-utilization hours.

E. Regulatory Review Costs

If regulations impose administrative costs on reviewers, such as the time

needed to read and interpret the proposed rule, then we should estimate the cost associated with regulatory review. We have received approximately 2,000 comments specific to the provisions of our recent proposed rules, and we estimate that a similar number will review this rule upon publication in the **Federal Register**.

Using the BLS wage information for medical and health service managers (code 11-9111), we estimate that the cost of reviewing this proposed rule is \$132.44 per hour, including fringe benefits, overhead, and other indirect costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 10 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore \$1,324.40 (10 hours × \$132.44). Therefore, we estimated that the maximum total cost of reviewing the proposed rule is \$2.6 million (\$1,324.40 × 2,000 reviewers). However, we expected that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but review just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the proposed rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be \$0.3 million.

We noted that this analysis assumes one reader per contract. Some alternatives included assuming one reader per parent organization. Using parent organizations instead of contracts would reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The rationale for this is that a parent organization might have local reviewers assessing potential region-specific effects from the rule.

F. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision. As required by OMB Circular A-4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>, in Table K6, we have prepared an accounting statement showing the transfers and costs associated with the provisions of this rule over an 11-year period or for contract years 2026 through 2036.

TABLE K6: ACCOUNTING STATEMENT -CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS, CONTRACT YEARS 2026-2036 (MILLIONS)

Category	3% Discount Rate	7% Discount Rate
<i>COSTS</i>		
Annualized monetized costs	-\$8.9	-\$8.7
<i>TRANSFERS</i>		
Annualized monetized transfers	\$1,183.6	\$1,156.3
From Federal Government to MA Organizations and PD Sponsors		

G. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

We believe this proposed rule will have a direct economic impact on beneficiaries, health insurance plans, and third-party marketing organizations (TPMOs). Based on the size standards set by the Small Business Administration (SBA) effective March 17, 2023, (for details, see the Small Business Administration's website at <https://www.sba.gov/document/support-table-size-standards>), Direct Health and Medical Insurance Carriers, classified using the NAICS code 524114, have a \$47 million threshold for "small size." Many Medicare Advantage organizations (about 30 to 40 percent) are not-for-profit, which allows them to qualify as "small entities" so long as they are independently owned and operated and nondominant in their field. We believe all of the not-for-profit organizations qualify as small under the aforementioned criteria. Of the 1,069 businesses using this NAICS code, we believe 799 (or 74.8 percent) are small businesses. Third party marketing organizations, which CMS has usually determined to belong to the category of Insurance Agencies and Brokerages (NAICS code of 524210), have a small size threshold of \$15 million. In total, 98.9 percent (119,114 out of 120,434) are considered small.

We are certifying that, if finalized, this rule will not have a significant economic impact on a substantial number of small entities. The analysis in this rule provides descriptions of the statutory provisions, identifies the policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analysis discussed in this section and throughout the preamble of this

proposed rule constitutes our RFA analysis. The RFA does not define the terms "significant economic impact" or "substantial number." The SBA advises that this absence of statutory specificity allows what is "significant" or "substantial" to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a "significant economic impact" to be 3 to 5 percent or more of the affected entities' costs or revenues, and a "substantial number" to mean 5 percent or more of affected small entities within a given industry. To explain our position, we will first note certain operational aspects of the Medicare program.

Each year, MA organizations submit a bid for each plan for furnishing Parts A and B benefits and the entire bid amount is paid to the plan by the government through the Medicare Trust Funds, if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that, historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees). Part D sponsors also submit a bid for each plan, and the payments made to stand-alone Part D plans (PDPs) are covered by the Supplementary Medical Insurance Medicare Trust Fund. PACE organizations are paid a capitation amount that is funded by both the Medicare Trust Funds (the Hospital Insurance and Supplementary Medical Insurance trust funds) as well as the State Medicaid programs they contract with.

MA plans can also offer enhanced benefits—that is, benefits not covered under Traditional Medicare. These enhanced benefits are paid for through enrollee premiums, rebates or a combination. Under the statutory payment formula, if the plan bid submitted by an MA organization for furnishing Part A and B benefits is lower than the administratively set

benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is, benefits not covered under Traditional Medicare) and/or to lower beneficiary cost sharing, Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

Part D sponsors submit bids and plans are paid through a combination of Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries, Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by the government and, in some cases, by enrollee premiums. As a result, MA plans, Part D plans, Prescription Drug Plans, and PACE organizations are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

The preceding analysis shows that meeting the direct cost of the rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA. Besides the direct costs discussed earlier, there are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of MA plans (including MA-PD plans) bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government, given that as previously noted, under the statutory payment formula, if a bid submitted by a MA plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate, which must be used

to provide supplemental benefits and/or lower beneficiary cost sharing, Part B or Part D premiums. If the plan's bid exceeds the administratively set benchmark, the beneficiary pays the difference in the form of a basic premium. However, as also noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of plans. If the provisions of the rule were to cause bids to increase and if the benchmark remains unchanged or increases by less than the bid does, the result could be a reduced rebate. Plans have different ways to address this in the short-term, such as reducing administrative costs, modifying benefit structures, and/or adjusting profit margins. These decisions may be driven by market forces. Part of the challenge in pinpointing the indirect effects is that there are many other factors combining with the effects of the rule, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits.

As indicated in Table K1, the proposals described in this rule are expected to result in cost savings amounting to approximately \$9.1 million in 2027 and \$9.7 million in subsequent years. Most affected entities are expected to have cost savings as a result of this rule. For example, we anticipate that the 697 MA organizations will experience a net cost savings despite some new costs. The Special Enrollment Period for Provider Terminations provision is expected to result in new costs of \$775,064 in 2027 for 697 MA organizations, equal to \$1,112 per organization. The provisions on Removing Rules on Time and Manner of Beneficiary Outreach are expected to reduce costs for 697 MA organizations by over \$45,000 in 2027, while the provision Rescinding the Annual Health Equity Analysis of Utilization Management Policies and Procedures is expected to lower costs for 697 MA organizations by \$813,805 in 2027 and \$785,367 annually in subsequent years. Likewise, the provision Rescinding the Mid-Year Supplemental Benefits Notice is estimated to result in \$1,854,611 in cost savings for 774 MA organization contracts in 2026 and \$1,355,520 annually thereafter, or \$2,396 in year one and \$1,751 per year after that. For those Medicare Advantage organizations to which all of these provisions apply, expected net cost savings will be \$2,396 for 2026, \$1,874 for 2027, and \$2,878 per year starting in 2028.

Many of the other entities affected by the provisions of this proposed rule are similarly expected to see cost savings, though others will see negligible cost increases. The provision Removing Account-based Medical Plans from Entities Required to Provide Creditable Coverage Disclosures is expected to save 7,049 group health plans about \$90,000 collectively every year, or approximately \$13 per entity. The provision revising the requirement that TPMOs retain calls for six years is expected to save organizations \$6.72 million annually starting in 2027. The passive enrollment provision is expected to result in additional costs of \$201,881 annually for an estimated 11 D-SNP contracts, or \$18,353 per contract. Any D-SNPs participating in passive enrollment would be approved to do so after consulting with the State Medicaid agency that contracts with the D-SNP and when CMS determines that the passive enrollment will promote continuity of care and integrated care. In most cases, these entities would be expected to benefit from the aforementioned cost savings this rule will produce for MA organizations, and so any D-SNPs approved to participate in passive enrollment would likely incur net costs of \$16,479 in 2027, while for 2028 and thereafter the net costs would be \$15,475 per contract.

We reiterate our belief that this proposed rule will not have a significant economic impact on a substantial number of small entities. In the case of TPMOs, though we do not know how many are operating in the Medicare space, this rule is expected to produce cost savings for them. The vast majority of MA organizations are likewise expected to see cost savings as a result of this rule. Even among the D-SNPs that are expected to incur new net costs, these costs are not expected to have a significant economic impact. The threshold to qualify as a small business for Direct Health and Medical Insurance Carriers is \$47 million of average annual receipts. Presuming some may be very small entities, we may estimate that a few have much smaller annual receipts than the threshold established by the SBA. The 2022 Economic Census indicates that insurance firms with fewer than 10 employees averaged nearly \$3.6 million in receipts for that year.¹²⁸ Even if receipts have not increased in the years since, the costs incurred by a D-SNP would likely fall well below HHS's 3 to 5 percent

threshold for significance. Finally, we also reiterate that Medicare Advantage organizations, including D-SNPs, are expected to include the costs of compliance in their bids. For these reasons, we do not believe these costs result in a significant economic impact on the affected plans. We request comment on the assessment of this rule's impact on small businesses.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of 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 2025, that threshold is approximately \$187 million. This proposed rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of \$187 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

J. Executive Order (E.O.) 14192, "Unleashing Prosperity Through Deregulation"

E.O. 14192, titled "Unleashing Prosperity Through Deregulation" was issued on January 31, 2025, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action. We estimate that this rule generates \$8

¹²⁸ US Census Bureau, 2022 SUSB Annual Data Tables by Establishment Industry, <https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html>, accessed September 22, 2025.

million in annualized cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

K. Conclusion

This proposed rule, if finalized, will result in net annualized cost savings ranging between \$8.9 and \$8.7 million for calendar years 2026 to 2036, at the 3% and 7% discount rates, respectively. These savings are primarily attributable to the provision revising aspects of TPMO oversight. This proposed rule will also result in net annualized monetized transfers ranging between \$1.18 billion and \$1.16 billion for calendar years 2026 to 2036, at the 3% and 7% discount rates respectively. These transfers primarily result from changing aspects of the MA and Part D Plan Quality Ratings System.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 2. Section 422.60 is amended by—

■ a. Revising paragraphs (g)(2)(i) and (2)(ii); and

■ b. In paragraph (g)(2)(vi) removing the phrase “capacity to passively” and adding in its place the phrase “capacity, including care coordinator staffing capacity, to passively”.

The revisions read as follows:

§ 422.60 Election process.

* * * * *

(g) * * *

(2) * * *

(i) Operate as an applicable integrated plan as defined at § 422.561.

(ii) Provide continuity of care for all incoming enrollees that complies with § 422.112(b)(8)(i)(B), with the exception

that the minimum transition period is 120 days.

* * * * *

■ 3. Section 422.62 is amended by revising paragraphs (b)(3) introductory text, (b)(5) introductory text, (b)(20) introductory text, (b)(23) introductory text, (b)(23)(ii), (b)(23)(iii), and (b)(27) to read as follows.

§ 422.62 Election of coverage under an MA plan.

(b) * * *

(3) This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP. To be eligible, the individual must demonstrate to CMS that—

* * * * *

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction. This SEP requires CMS approval prior to use. The individual must receive a notice, as described in § 422.62(b)(5)(i), to make an election using this SEP.

* * * * *

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable. This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * * *

(b) * * *

(23) Individuals affected by a change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA plan or to original Medicare. This SEP can be used only once per change in the provider network.

* * * * *

(ii) An enrollee is affected by a network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) The MA plan that has changed its network must include in the provider termination notice described at § 422.111(e) information regarding the affected enrollee’s eligibility for the SEP and how to use the SEP.

* * * * *

(27) The individual meets such other exceptional conditions as CMS may provide. This SEP requires CMS approval prior to use. The individual must use a CMS-operated mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * * *

■ 4. Section 422.66 is amended by adding paragraph (g) to read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(d) * * *

* * * * *

(g) *Elections requiring prior CMS approval.*

(1) *CMS approval.* Special Election Periods specified in § 422.66(g)(2) require CMS approval before an individual can use the SEP to make an election.

(i) CMS approval is provided for MA plan elections either through the use of a CMS-operated election mechanism or through the individual’s receipt of a notice which explains eligibility for the SEP and election instructions.

(ii) MA plans may not transmit elections to CMS using the specified SEPs without prior CMS approval.

(2) *Special election periods.* All of the following SEPs require CMS approval prior to use:

(i) SEP for contract violation, § 422.62(b)(3).

(ii) SEP for individuals who disenroll in connection with CMS sanction, § 422.62(b)(5).

(iii) SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage, § 422.62(b)(20).

(iv) SEP for other exceptional circumstances, § 422.62(b)(27).

§ 422.101 [Amended]

■ 5. Section 422.101 is amended by—

■ a. In paragraph (f)(3)(iv)(B) removing the phrase “June 1st and November 30th of each calendar year” and adding in its place the phrase “January 1st and March 31st or October 1st and December 31st of each contract year”; and

■ b. In paragraph (f)(3)(iv)(G) removing the phrase “opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each year.” and adding in its place the phrase “opportunity per contract year to submit a corrected off-cycle revision between

January 1st and March 31st or October 1st and December 31st of each contract year.

§ 422.102 [Amended]

- 6. Section 422.102 is amended by—
- a. Removing and reserving paragraph (e); and
- b. In paragraph (f)(1)(iii)(G), removing the phrase “Cannabis products.” and adding in its place the phrase “Cannabis products that are illegal under applicable State or Federal law, including the Federal Food, Drug, and Cosmetic Act.”
- 7. Section 422.107 is amended by adding paragraph (d)(1)(i) and adding and reserving paragraph (d)(1)(ii) to read as follows:

§ 422.107 Requirements for dual eligible special needs plans.

- * * * * *
- (d) * * *
- (1) * * *
- (i) In conjunction with § 422.514(h), to the extent that a State Medicaid agency contract allows a dual eligible special needs plan established through this paragraph (d)(1) to enroll full benefit dually eligible beneficiaries, the contract must stipulate that such full benefit dually eligible beneficiaries cannot be enrolled in a Medicaid managed care organization that is owned and controlled by an entity other than the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization.
- (ii) [Reserved]
- * * * * *

§ 422.111 [Amended]

- 8. Section 422.111 is amended by removing paragraph (I).
- 9. Section 422.112 is amended by revising paragraph (a)(8) to read as follows:

§ 422.112 Access to services.

- * * * * *
- (a) * * *
- (8) *Cultural considerations.* Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.
- * * * * *

§ 422.137 [Amended]

- 10. Section 422.137 is amended by removing paragraphs (c)(5), (d)(6), and (d)(7).

§ 422.152 [Amended]

- 11. Section 422.152 is amended by removing paragraph (a)(5).

- 12. Section 422.164 is amended by revising paragraph (e)(2) and adding paragraph (e)(3) to read as follows:

§ 422.164 Adding, updating, and removing measures.

- * * * * *
- (e) * * *
- (2) CMS will announce the removal of a measure based upon its application of paragraph (e)(1) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period or will propose and finalize the removal of the measure through rulemaking in advance of the measurement period.
- (3) CMS will propose and finalize the removal of a measure for any reason not stated in paragraph (e)(1) of this section through rulemaking in advance of the measurement period.
- * * * * *

- 13. Section 422.166 is amended by—
- a. In paragraph (f)(1) removing the phrase “Through the 2026 Star Ratings, this rating-specific” and adding in its place the phrase “This rating-specific”;
- b. Removing paragraph (f)(3); and
- c. Revising paragraph (h)(2) to read as follows:

§ 422.166 Calculation of Star Ratings.

- * * * * *
- (h) * * *
- (2) *Plan preview of the Star Ratings.* CMS will have two plan preview periods before each Star Ratings release during which MA organizations can preview their preliminary Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the second plan preview, CMS will display de-identified contract-level sample data for one of each type of measure needed to replicate the cut point methodology, as determined by CMS.
- * * * * *

§ 422.308 [Amended]

- 14. Section 422.308 is amended in paragraph (c)(1) by removing the word “gender” and adding in its place the word “sex”.
- 15. Section 422.310 is amended by revising paragraph (f) to read as follows:

§ 422.310 Risk adjustment data.

- * * * * *
- (f) *Use and release of data.* Regarding the data described in paragraphs (a) through (d) of this section, CMS may use and release the minimum data it determines is necessary in accordance with CMS data sharing procedures and applicable Federal laws, subject to the aggregation of dollar amounts reported

for the associated encounter to protect commercially sensitive data, unless authorized by other applicable laws.

* * * * *

- 16. Section 422.510 is amended by adding paragraphs (a)(4)(xvii), (b)(2)(i)(D), and (c)(2)(iv) to read as follows:

§ 422.510 Termination of contract by CMS.

- (a) * * *
- (4) * * *
- (xvii) Is no longer eligible to offer a dual eligible special needs plan because the MA organization does not hold a contract consistent with § 422.107(b) with the State Medicaid agency.
- (b) * * *
- (2) * * *
- (i) * * *
- (D) The contract is being terminated based on § 422.510(a)(4)(xvii).
- (c) * * *
- (2) * * *
- (iv) The contract is being terminated based on paragraph (a)(4)(xvii) of this section.
- * * * * *

- 17. Section 422.514 is amended by adding paragraphs (h)(3)(iii), (iv), and (v) to read as follows:

§ 422.514 Enrollment requirements.

- * * * * *
- (h) * * *
- (3) * * *
- (iii) If the State Medicaid agency’s contract with the MA organization permits full benefit dually eligible beneficiaries to be enrolled in a plan that is not a HIDE SNP or FIDE SNP per § 422.107(d)(1)(i), or a HIDE SNP with the majority of its enrollees in Medicaid fee-for-service, the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization may offer one or more additional D-SNPs for full benefit dual eligible individuals in the same service area.

- (iv) MA organizations with D-SNPs subject to paragraph (h)(3)(iii) must comply with responsibilities at § 422.562(a)(5).

- (v) If a U.S. Territory has not adopted Medicare Savings Programs, as defined in 42 CFR 435.4, an MA organization operating in such U.S. Territory is exempt from the requirements in paragraph (h)(1)(i) of this section.

§ 422.752 [Amended]

- 18. Section 422.752 is amended by removing and reserving paragraph (d).
- 19. Section 422.2261 is amended by adding paragraph (a)(3) to read as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) * * *

(3)(i) MA organizations offering dual eligible special needs plans with exclusively aligned enrollment subject to § 422.107(e) must submit all materials for the contract in HPMS under the MA organization's contract number.

(ii) MA organizations and third-party marketing organizations may not submit materials for the contract under the organization's Multi-Contract Entity number as described in § 422.2262(d)(2)(i).

* * * * *

§ 422.2262 [Amended]

■ 20. Section 422.2262 is amended by removing paragraphs (a)(1)(i) and (a)(1)(ii) and redesignating paragraphs (a)(1)(iii) through (xix) as paragraphs (a)(1)(i) through (xvii), respectively.

* * * * *

■ 21. Section 422.2264 is amended by—

■ a. In paragraph (c)(1)(ii)(D), removing the phrase “Cards, but not including Scope” and adding in its place “Cards and Scope”; and

■ b. Revising paragraphs (c)(2)(i), (c)(3) introductory text, and (c)(3)(i).

The revisions read as follows:

§ 422.2264 Beneficiary contact.

* * * * *

(c) * * *

(2) * * *

(i) If a marketing event directly follows an educational event, the beneficiary must be notified that the educational event is ending and a marketing event will begin shortly and be given a sufficient opportunity to leave the educational event prior to the start of the marketing event.

* * * * *

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple) for purposes of discussing marketing topics. Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies). The Scope of Appointment must be in writing for in-person personal marketing appointments.

* * * * *

■ 22. Section 422.2267 is amended by—

■ a. Revising paragraphs (e)(5)(ii)(B)(1) and (e)(12)(ii)(D);

■ c. Removing and reserving paragraph (e)(31);

■ d. Revising paragraph (e)(41) introductory text and (e)(41)(ii); and

■ e. Removing paragraph (e)(42).

The revisions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(5) * * *

(ii) * * *

(B) * * *

(1) Deductible; the initial coverage phase; coverage gap for a year preceding 2025; and catastrophic coverage.

* * * * *

(12) * * *

(ii) * * *

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is affected by the provider termination is eligible for a special election period, as specified in § 422.62(b)(23) (including the start and end dates of that SEP), and Medigap guaranteed issue (GI) rights. The notice must advise individuals who have coverage through an employer or union to contact their benefits administrator before leaving their current MA plan to find out how making such a change may affect their employer or union health benefits.

* * * * *

(31) [Reserved]

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all MA organizations in the service area the disclaimer consists of the statement: “We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov* or 1–800–MEDICARE to get information on all of your options.” If the TPMO sells for all MA organizations in the service area the disclaimer consists of the statement: “Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov* or 1–800–MEDICARE for help with plan choices.” The MA organization must ensure that the disclaimer is as follows:

* * * * *

(ii) Verbally conveyed during sales calls prior to the discussion of any benefits.

* * * * *

■ 23. Section 422.2274 is amended by—

■ a. In paragraph (b)(3), removing the phrase “prior to meeting with potential enrollees” and adding in its place “prior to a personal marketing appointment”; and

■ b. Revising paragraphs (c)(9) and (g)(2)(ii).

The revisions read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(9) Establish and maintain a system for confirming all of the following:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all personal marketing appointments (including telephonic and walk-in).

* * * * *

(g) * * *

(2) * * *

(ii) Record and retain for 6 years all marketing and sales calls, including the audio portion of calls via web-based technology, in their entirety.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 24. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 25. Section 423.1 is amended by adding “1860D–14C. Manufacturer Discount Program.” in numerical order in paragraph (a)(1) to read as follows:

§ 423.1 Basis and scope.

(a) * * *

(1) * * *

1860D–14C. Manufacturer Discount Program.

* * * * *

■ 26. Section 423.4 is amended by adding the definitions of “Geographic area”, “Outlier prescriber of opioids”, “Persistent outlier prescriber of opioids”, and “Specialty” in alphabetical order to read as follows:

§ 423.4 Definitions

* * * * *

Geographic area means the state in which a prescriber is practicing.

* * * * *

Outlier prescriber of opioids means a prescriber who is a statistical outlier compared to their peers in a specialty and geographic area.

* * * * *

Persistent outlier prescriber of opioids means an outlier prescriber identified by CMS in three consecutive outlier prescriber notifications.

* * * * *

Specialty means the National Plan Provider Enumeration System (NPPE) taxonomy of a prescriber.

* * * *

■ 27. Section 423.32 is amended by adding paragraph (k) to read as follows:

§ 423.32 Enrollment process.

* * * *

(k) *Enrollments requiring prior CMS approval*—

(1) *CMS approval*. Special Election Periods specified in § 423.32(k)(2) require CMS approval before an individual can use the SEP to make an enrollment election. CMS approval is provided for Part D enrollments either through the use of a CMS-operated election mechanism or through the individual's receipt of a notice which explains eligibility for the SEP and election instructions. Part D plans may not transmit enrollment elections to CMS using the specified SEPs without prior CMS approval.

(2) *Special election periods*. All of the following SEPs require CMS approval prior to use:

(i) SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage, § 423.38(c)(2).

(ii) SEP for contract violation, § 423.38(c)(8).

(iii) SEP for individuals who disenroll in connection with CMS sanction, § 423.38(c)(12).

(iv) SEP for other exceptional circumstances, § 423.38(c)(36).

* * * *

■ 28. Section 423.36 is amended by adding paragraph (g) to read as follows:

§ 423.36 Disenrollment process.

* * * *

(g) *Disenrollments requiring prior CMS approval*—

(1) *CMS approval*. Special Election Periods specified in § 423.36(g)(2) require CMS approval before an individual can use the SEP to make a disenrollment election. CMS approval is provided for Part D disenrollments either through the use of a CMS-operated election mechanism or through the individual's receipt of a notice which explains eligibility for the SEP and election instructions. Part D plans may not transmit disenrollment elections to CMS using the specified SEPs without prior CMS approval.

(2) *Special election periods*. All of the following SEPs require CMS approval prior to use:

(i) SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage, § 423.38(c)(2).

(ii) SEP for contract violation, § 423.38(c)(8).

(iii) SEP for individuals who disenroll in connection with CMS sanction, § 423.38(c)(12).

(iv) SEP for other exceptional circumstances, § 423.38(c)(36).

* * * *

■ 29. Section 423.38 is amended by revising paragraphs (c)(2), (c)(8), (c)(12) introductory text, and (c)(36) to read as follows:

§ 423.38 Enrollment periods.

* * * *

(c) * * *

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage. This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * *

(8) This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP. The individual must demonstrate to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to any of the following:

* * * *

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction. This SEP requires CMS approval prior to use. The individual must receive a notice, as described in paragraph (c)(12)(i) of this section, to make an election using this SEP.

* * * *

(36) The individual meets other exceptional circumstances as CMS may provide. This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * *

■ 30. Section 423.56 is amended by revising paragraphs (a) and (b)(3) to read as follows:

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition*. Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount provided under section 1860D–14C of the Act, and demonstrated through—

(1) The use of generally accepted actuarial principles and in accordance with CMS guidelines; or

(2) For group health plans not receiving a retiree drug subsidy, meeting the following requirements under the simplified creditable coverage determination methodology:

(i) Provision of reasonable coverage for brand name and generic prescription drugs and biological products.

(ii) Provision of reasonable access to retail pharmacies.

(iii) Is designed to pay on average a minimum percent of participants' prescription drug expenses, with the percent value at 73 percent for 2027 and percent values for subsequent years to be updated by CMS in subregulatory guidance in a time and manner determined by CMS to reflect the actuarial value of defined standard prescription drug coverage under Part D.

* * * *

(b) * * *

(3) Coverage under a group health plan (other than an account-based medical plan as defined at 42 CFR 423.882 (paragraph (4) of the definition of Group health plans)) including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

* * * *

■ 31. Section 423.100 is amended by—

■ a. Revising and republishing the definition of “Applicable beneficiary”;

■ b. Adding the definition of “Applicable discount” in alphabetical order;

■ c. Revising and republishing the definition of “Applicable drug”;

■ d. Adding the definition of “Applicable number of calendar days” in alphabetical order;

■ e. Revising and republishing the definition of “Coverage gap”;

■ f. Adding the definition of “Date of dispensing” in alphabetical order;

■ g. Revising and republishing the definition of “Incurred costs”;

■ f. Adding definitions for “Labeler code”, “Manufacturer”, “Manufacturer Discount Program”, “Manufacturer Discount Program agreement”, “Medicare Coverage Gap Discount Program”, “Medicare Coverage Gap Discount Program agreement”, “National Drug Code (NDC)”, “Non-applicable drug”, “Price applicability period”, “Selected drug”, and “Third Party Administrator (TPA)” in alphabetical order.

The additions and revisions read as follows:

§ 423.100 Definitions

* * * * *

Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA–PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3)(i) For the purposes of the Coverage Gap Discount Program—

(A) Is not entitled to an income-related subsidy under section 1860D–14(a) of the Act;

(B) Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year;

(C) Has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and

(D) Has a claim that—

(1) Is within the coverage gap;

(2) Straddles the initial coverage period and the coverage gap;

(3) Straddles the coverage gap and the annual out-of-pocket threshold; or

(4) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold; and

(ii) For the purposes of the Manufacturer Discount Program, has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that exceed the annual deductible specified in section 1860D–2(b)(1) of the Act.

Applicable discount, for purposes of the—

(1) Coverage Gap Discount Program, has the meaning set forth at § 423.2305; and

(2) Manufacturer Discount Program, has the meaning set forth at § 423.2712.

Applicable drug means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351).

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary; or

(iv) For the purposes of the Manufacturer Discount Program, is provided to a particular applicable beneficiary as a transition fill under § 423.120(b)(3) or as an emergency supply as may be required for an applicable beneficiary who is a long-term care resident.

(3) Not a compounded drug product (as described in § 423.120(d)) that contains an applicable drug; and

(4) For the purposes of the Manufacturer Discount Program, not a selected drug during a price applicability period with respect to such drug.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

* * * * *

Coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold during the years 2006 through 2024. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

* * * * *

Date of dispensing means the date of service. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

* * * * *

Incurred costs means costs incurred by a Part D enrollee—

(1) For—

(2) * * *

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

(3) For 2025 and subsequent years, that are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program under subpart AA of this part.

* * * * *

Labeler code means the first segment of the National Drug Code (NDC) that identifies a particular manufacturer.

* * * * *

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Coverage Gap Discount Program and the Manufacturer Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Manufacturer Discount Program means the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

Manufacturer Discount Program agreement means the agreement described at section 1860D–14C(b) of the Act.

Medicare Coverage Gap Discount Program (or Coverage Gap Discount Program) means the Medicare Coverage Gap Discount Program established under section 1860D–14A of the Act.

Medicare Coverage Gap Discount Program agreement (or Coverage Gap Discount Program agreement) means the agreement described in section 1860D–14A(b) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product's manufacturer, product and package size and type.

Non-applicable drug means any Part D drug that is not an applicable drug and not a selected drug during a price applicability period with respect to such drug.

Price applicability period has the meaning given such term in section 1191(b)(2) of the Act and any applicable regulations and guidance.

Selected drug has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by CMS to carry out sections 1860D–14A and 1860D–14C of the Act.

■ 32. Section 423.104 is amended by—

■ a. Revising paragraphs (d)(1) introductory text, (d)(2) introductory text, (d)(2)(i) introductory text, (d)(2)(iv)(A)(4), (d)(2)(iv)(B), and (d)(2)(iv)(D)(3);

■ b. Revising and republishing paragraph (d)(3);

■ c. Revising paragraphs (d)(4) introductory text, (d)(4)(iii)(C), and (d)(4)(iv)(E).

■ d. Removing paragraph (d)(4)(iv)(F);

■ e. Adding paragraph (d)(4)(v);

■ f. Revising paragraphs (d)(5)(i) introductory text, (d)(5)(i)(A)(2), and (d)(5)(iii)(F).

■ g. Adding paragraphs (d)(5)(iii)(G) and (H);

■ h. Adding paragraphs (d)(5)(iv)(A), (B), (C) and (D);

■ i. Revising paragraphs (e)(5) introductory text, (e)(5)(i), and (f)(1)(ii)(B)(3).

■ j. Adding paragraph (j).

The revisions and additions read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

(d) * * *

(1) *Deductible.* Subject to § 423.120(g) and (h), an annual deductible equal to—

(2) *Cost-sharing under prescription drug plans.*

(i) Subject to paragraph (d)(4) of this section, coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and for each year preceding 2025, up to the initial coverage limit under paragraph (d)(3) of this section, and for 2025 and each subsequent year, up to the annual out-of-pocket threshold specified in paragraph (d)(5)(iii) of this section, that is—

(iv) * * *

(A) * * *

(4) *Determination.* Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iv)(A)(3) of this section is the specialty-tier cost threshold for the plan year.

(B) * * *

(1) CMS modifies the specialty-tier cost threshold for a plan year only if the

amount determined in paragraph (d)(2)(iv)(A)(3) of this section for a plan year is at least 10 percent above or below the specialty tier cost threshold for the prior plan year.

(2) If a modification is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(3) of this section to the nearest \$10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

(D) * * *

(3) For Part D plans with a deductible that is greater than \$0 and less than the deductible provided under the Defined Standard benefit, the maximum coinsurance percentage is determined as follows:

(i) For years preceding 2025, subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

(ii) For 2025 and each subsequent year, dividing the annual out-of-pocket (OOP) threshold, described in paragraph (d)(5)(iii) of this section, by total drug costs (represented by subtracting the plan deductible from the annual OOP threshold then dividing by the intended specialty-tier coinsurance percentage and adding the plan deductible) such that the result is 33 percent. Using the following equation solved for the deductible, each maximum allowable specialty-tier coinsurance percentage point can be inserted to determine the maximum allowable deductible corresponding to that coinsurance.

$$\frac{(\text{OOP Threshold})}{\left(\frac{(\text{OOP Threshold} - \text{Deductible})}{(\text{Maximum allowable specialty tier coinsurance} + \text{Deductible})} \right)} = 33\%$$

(3) *Initial coverage limit.* The initial coverage limit is equal to one of the following:

(i) For 2006, \$2,250.

(ii) For years 2007 through 2024. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$10.

(iii) For year 2025 and each subsequent year, there is no initial coverage limit.

(4) *Cost-sharing in the coverage gap for applicable beneficiaries.* For a year preceding 2025, cost-sharing in the coverage gap for applicable beneficiaries is as follows:

(iii) * * *

(C) For 2020 through 2024, 25 percent.

(iv) * * *

(E) For 2019 through 2024, 75 percent.

(v) For 2025 and each subsequent year, there is no coverage gap.

(5) * * *

(i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, for 2024 and each subsequent year, cost-sharing equal to \$0, and for each year preceding 2024, cost-sharing equal to the greater of—

(A) * * *

(2) For subsequent years through 2023, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage

increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

* * * *

(iii) * * *

(F) *For 2021 through 2024.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest \$50.

(G) *For 2025.* \$2,000.

(H) *For 2026 and each subsequent year.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest \$50.

* * * *

(iv) *Annual percentage increase in Part D drug expenditures.*

(A) *General.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(B) *Calculating the annual percentage increase.* The annual percentage increase is the product of the annual percentage trend (as defined in subparagraph (C) of this paragraph) and a multiplicative update (as defined in subparagraph (D) of this paragraph).

(C) *Annual percentage trend.* The annual percentage trend for a given year is the ratio of total Part D drug expenditures in the previous year (numerator) to the total Part D drug expenditures two years prior to the given year (denominator).

(D) *Multiplicative update.* The multiplicative update for a given year is the ratio of the product of the annual percentage trends for all prior recorded years as revised and updated with the most recently available data (numerator) to the product of annual percentage trends in prior recorded years as published in the previous year's rate announcement (denominator).

* * * *

(e) * * *

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section for a year preceding 2025, or the annual out-of-pocket threshold specified in paragraph (d)(5)(iii) for the year for 2025 and each subsequent year, of an amount equal to at least the product of the following:

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year, for a year preceding 2025, or the annual out-of-pocket threshold described in paragraph (d)(5)(iii) for the year for 2025 and each subsequent year, exceeds the deductible described in paragraph (d)(1) of this section.

* * * *

(f) * * *

(1) * * *

(ii) * * *

(B) * * *

(3) For a year preceding 2025, an increase in the initial coverage limit described in paragraph (d)(3) of this section.

* * * *

(j) *Drugs not subject to the defined standard deductible.*

(1) If a beneficiary has not satisfied their plan deductible but has accumulated sufficient incurred costs, as defined at § 423.100, to satisfy the deductible provided under the Defined Standard benefit, then they will be both an applicable beneficiary under the Manufacturer Discount Program, as defined at § 423.100, and be deemed to have satisfied their plan deductible.

(2) If a plan offers a deductible other than the deductible provided under the Defined Standard benefit and a beneficiary accumulates sufficient incurred costs, as defined at § 423.100, to satisfy the plan deductible but has not accumulated incurred costs across all drugs at or above the deductible provided under the Defined Standard benefit, then applicable discounts, as defined at § 423.2712, under the Manufacturer Discount Program are not available for that beneficiary and the plan must cover the portion of the costs that would be covered by the applicable discount if the beneficiary were an applicable beneficiary until the beneficiary's incurred costs exceed the deductible provided under the Defined Standard benefit and they become an applicable beneficiary.

(3) If a plan offers a deductible other than the deductible provided under the Defined Standard benefit and a beneficiary accumulates sufficient incurred costs, as defined at § 423.100, to satisfy the plan deductible but has not accumulated incurred costs across all drugs at or above the deductible provided under the Defined Standard benefit, then the selected drug subsidy is not available for that beneficiary and the plan must cover the portion of the costs that would be covered by the selected drug subsidy, as described at § 423.329(e), if the beneficiary were an applicable beneficiary until the

beneficiary's incurred costs exceed the deductible provided under the Defined Standard benefit and they become an applicable beneficiary.

■ 33. Section 423.128 is amended by revising paragraphs (e)(3)(ii) and (e)(7) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * *

(e) * * *

(3) * * *

(ii) For a year preceding 2025, the initial coverage limit for the current year.

* * * *

(7) Be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including, for a year preceding 2025, the covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

* * * *

■ 34. Section 423.184 is amended by revising paragraph (e)(2) and adding paragraph (e)(3) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * *

(e) * * *

(2) CMS will announce the removal of a measure based upon its application of paragraph (e)(1) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period or will propose and finalize the removal of the measure through rulemaking in advance of the measurement period.

(3) CMS will propose and finalize the removal of a measure for any reason not stated in paragraph (e)(1) of this section through rulemaking in advance of the measurement period.

* * * *

§ 423.186 [Amended]

■ 35. Section 423.186 is amended by—

■ a. In paragraph (f)(1) removing the phrase “Through the 2026 Star Ratings, this rating-specific” and adding in its place the phrase “This rating-specific”;

■ b. Removing paragraph (f)(3); and

■ c. Revising paragraph (h)(2) to read as follows:

§ 423.186 Calculation of Star Ratings.

* * * *

(h) * * *

(2) *Plan preview of the Star Ratings.* CMS will have two plan preview periods before each Star Ratings release

during which Part D plan sponsors can preview their preliminary Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the second plan preview, CMS will display de-identified contract-level sample data for one of each type of measure needed to replicate the cut point methodology, as determined by CMS.

* * * * *

■ 36. Section 423.265 is amended by adding paragraph (d)(2)(vi) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(d) * * *

(2) * * *

(vi) The assumptions regarding the selected drug subsidy under § 423.329(e) used in calculating the bid.

* * * * *

■ 37. Section 423.286 is amended by revising and republishing paragraph (b) to read as follows:

§ 423.286 Rules regarding premiums.

* * * * *

(b) *Base beneficiary premium percentage.*

(1) The beneficiary premium percentage for any year, except for years 2024 through 2029, is a fraction, the—

(i) Numerator of which is 25.5 percent; and

(ii) Denominator of which is as follows:

(A) 100 percent minus the percentage established in paragraph (b)(1)(ii)(B) of this section

(B) The percentage established in this paragraph equals—

(1) The total reinsurance payment that CMS estimates will be paid under § 423.329(c) for the coverage year divided by—

(2) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(2) The beneficiary premium percentage for the years 2024 through 2029 is the lesser of the beneficiary premium percentage—

(i) For the immediately preceding year increased by 6 percent; or

(ii) Calculated under the formula computed under paragraph (b)(1)

* * * * *

■ 38. Section 423.308 is amended by—

■ a. Revising the definitions for “Allowable reinsurance costs” and “Gross covered prescription drug costs”; and

■ b. Adding the definition of “Inflation Reduction Act Subsidy Amount (IRASA)”.

The revisions and addition read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan and the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined at § 423.100 of this part) paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100 of this part). The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

* * * * *

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of actual costs (as defined at § 423.100) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464.

(2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined at § 423.100, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part

D plan consistent with the plan processes and instructions for the submission of such information.

(3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or, for years prior to 2025, amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or, for years prior to 2025, because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined at § 423.100 and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) All amounts paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100).

* * * * *

Inflation Reduction Act Subsidy Amount (IRASA) means a temporary retrospective subsidy paid to Part D plan sponsors for contract year 2023 for the statutory reduction in cost-sharing and deductible for covered insulin products or for ACIP-recommended adult vaccines, as defined in § 423.100, and is equal to the difference between the following:

(1) The beneficiary cost-sharing for a covered insulin product or an ACIP-recommended adult vaccine under the plan's approved bids submitted under § 423.265 for contract year 2023; and

(2) The applicable statutory maximum cost-sharing for the covered insulin product or for the ACIP-recommended adult vaccine for contract year 2023.

* * * * *

■ 39. Section 423.315 is amended by adding paragraph (h) to read as follows:

§ 423.315 General payment provisions.

* * * * *

(h) *Selected drug subsidy.* CMS provides selected drug subsidy payments described in § 423.329(e) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under

§ 423.329(e)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(e).

■ 40. Section 423.325 is amended by revising paragraph (a)(3) to read as follows:

§ 423.325 PDE submission timeliness requirements.

(a) * * *

(3) Revised PDE records to resolve CMS rejected records at least once every 90 calendar days from receipt of a rejection until the PDE record is accepted unless the claim associated with the rejected PDE record is reversed or deleted, or the PDE record is otherwise found to have been submitted in error.

* * * * *

■ 41. Section 423.329 is amended by revising paragraph (c)(1) and adding paragraph (e) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(c) *Reinsurance payment amount—*

(1) *General rule—*

(i) *General rule for years preceding 2025.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true-out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(ii) *General rule for 2026 and subsequent years.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 20 percent for applicable drugs or 40 percent for drugs that are not applicable drugs of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true-out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

* * * * *

(e) *Selected drug subsidy amount—*

(1) *General rule.* The selected drug subsidy amount is equal to 10 percent of the negotiated price to a covered Part D drug that would otherwise meet the definition of an applicable drug but for being a selected drug during a price applicability period.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the selected drug subsidy amount assumptions submitted with plan bids under § 423.265(d)(2)(vi) of this part and negotiated and approved under § 423.272 of this part, or by an alternative method that CMS determines.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred selected drug subsidy amounts as provided in § 423.343(e).

■ 42. Section 423.336 is amended by revising paragraph (c) to read as follows:

§ 423.336 Risk-sharing arrangements.

* * * * *

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS does not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

* * * * *

■ 43. Section 423.343 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 423.343 Retroactive adjustments and reconciliations.

* * * * *

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout

the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section.

(e) *Selected drug subsidy.* CMS makes final payment for selected drug subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim selected drug subsidy payments and total selected drug subsidy costs eligible for subsidy under § 423.329(e) submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the interim selected drug subsidy payments exceed the amount payable under § 423.329(e) of if the Part D sponsor does not provide the data in paragraph (e)(1) of this section.

* * * * *

■ 44. Section 423.346 is amended by revising paragraph (a) introductory text to read as follows:

§ 423.346 Reopening.

(a) CMS may conduct a global or targeted reopening to reopen and revise an initial or reconsidered final payment determination, including the following: a determination of the final amount of direct subsidy described at § 423.329(a)(1), final reinsurance payments described at § 423.329(c), final amount of the low income subsidy described at § 423.329(d), final risk corridor payments as described at § 423.336, reconciled Coverage Gap Discount Program payment described at § 423.2320(b), reconciled Inflation Reduction Act Subsidy Amount (IRASA) payment for contract year 2023 described at § 423.308, reconciled Manufacturer Discount Program payment described at § 423.2744(c), and

reconciled selected drug subsidy payment described at § 423.343(e)—

* * * * *

■ 45. Section 423.350 is amended by—
■ a. Adding paragraphs (a)(1)(vi) through (viii); and

■ b. Revising paragraphs (a)(2) and (b)(1).

The additions and revisions read as follows:

§ 423.350 Payment appeals.

(a) * * *

(1) * * *

(vi) The reconciled Inflation Reduction Act Subsidy Amount (IRASA) payment for contract year 2023 described at § 423.308.

(vii) The reconciled Manufacturer Discount Program payment under § 423.2744(c).

(viii) The reconciled selected drug subsidy payment under § 423.343(e).

(2) Payment information not subject to appeal. Payment information submitted to CMS under § 423.322 and reconciled or used in the payment calculations for the reconciled IRASA payment for contract year 2023 described at § 423.308 or under §§ 423.336, 423.343, 423.2320(b), or 423.2744(c) is final and may not be appealed, nor may the appeals process be used to submit new information after the submission of information necessary for CMS to determine retroactive adjustments and reconciliations, including the calculation of risk corridor costs.

(b) * * *

(1) *Time for filing a request.* The request for reconsideration must be filed within 15 calendar days from the date CMS issues the payment reconciliation report for the payment determination that is being appealed under this section by the Part D plan sponsor.

* * * * *

■ 46. Section 423.464 is amended by revising paragraph (f)(2)(i)(C) to read as follows:

* * * * *

(f) * * *

(2) * * *

(i) * * *

(C) Exclude expenditures for covered Part D drugs made by government-funded health programs or the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program.

* * * * *

■ 47. Section 423.504 is amended by adding paragraph (f) to read as follows:

§ 423.504 General provisions.

* * * * *

(f) *Outlier prescribers of opioids.*

(1) CMS will identify and send notifications to outlier prescribers of opioids, which includes information about how the prescriber compares to other specified prescribers and resources on proper prescribing methods.

(2) At least annually, CMS will communicate information about persistent outlier prescribers of opioids to all Part D plan sponsors.

■ 48. Section 423.505 is amended by—

■ a. Revising paragraph (b)(24);

■ b. Adding paragraphs (d)(1)(vi) and (d)(2)(xiii); and

■ c. In paragraph (e)(2), removing the phrase “under the contract, or” and adding in its place the phrase “under the contract, which includes the records containing information identified in paragraph (d) of this section, or “.

The additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(24) Provide applicable discounts on applicable drugs when dispensed to applicable beneficiaries in accordance with the requirements in subpart W of part 423 for the Coverage Gap Discount Program and the requirements in subpart AA of part 423 for the Manufacturer Discount Program.

* * * * *

(d) * * *

(1) * * *

(vi) Enable CMS to review original format documentation or information from all written, electronic, and verbal communications between the pharmacist, prescriber, enrollee, or other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon by the Part D plan sponsor to make a coverage determination or otherwise permit a point-of-sale claim adjudication that determine a drug’s coverage under the Part D benefit. In instances when a coverage determination is extended, the original coverage determination must be maintained as documentation. The documentation covered by these standards must be made available to CMS during Part D program integrity prescription drug event (PDE) record review audits. Failure to produce this documentation will result in an improper Part D audit determination and will be subject to PDE record deletion in accordance with § 423.325(a)(2).

(2) * * *

(xiii) Documentation or information from all written, electronic, and verbal communications between the pharmacist, prescriber, enrollee, or

other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon when Part D plan sponsors make coverage determinations or otherwise permit a point-of-sale claim adjudication that determines coverage of a drug under the Part D benefit, consistent with paragraph (d)(1)(vi). This includes:

(A) Date and time the request for a coverage determination or point-of-sale claim adjudication was received and the identity of the individual who submitted the request.

(B) Name and title (as applicable) of the individual the Part D plan contacted to verify the request (for example, pharmacist, prescriber, enrollee, or enrollee representative).

(C) Information obtained, including the questions asked and responses received, and the final decision rendered.

(D) Diagnosis code for a coverage determination or point-of-sale claim adjudication used to support a medically accepted indication.

(E) Any other information that the Part D plan sponsor utilized to determine the final outcome of the coverage determination or point-of-sale claim adjudication request.

* * * * *

■ 49. Section 423.782 is amended by—

■ a. Revising paragraphs (a)(2) introductory text and (a)(2)(i)(B);

■ b. In paragraph (a)(2)(iii)(A), removing the phrase “Index, rounded” and adding in its place the phrase “Index specified in paragraph (d) of this section, rounded”;

■ c. In paragraph (b)(1), removing the phrase “Part D drugs, rounded to” and adding in its place the phrase “Part D drugs, rounded as specified under § 423.104(d)(5)(iv) to”;

■ d. In paragraph (b)(3), removing the phrase “in this paragraph (b)(3) for the previous years increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded” and adding in its place the phrase “in § 423.104(d)(5)(i)(A)(2), rounded”; and

■ d. Adding paragraph (d).

The addition reads as follows:

§ 423.782 Cost-sharing subsidy.

* * * * *

(a) * * *

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA–PD plan below the out-of-pocket limit (under § 423.104), including for years preceding 2025, Part D drugs covered under the PDP or MA–PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) * * *

(B) Those individuals who have income for years prior to 2024 under 135 percent, and for 2024 and subsequent years, under 150 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

* * * * *

(d) *Annual percentage increase in consumer price index (CPI).*

(1) *General.* The annual percentage increase in consumer price index (CPI) for each year is equal to the annual percentage increase in the CPI in the United States for all items per a U.S. city average and is based on data for the 12-month period ending in September of the previous year.

(2) *Calculating the annual percentage increase in CPI.* The annual percentage increase is the product of the annual percentage trend (as defined in subparagraph (d)(3) of this section) and a multiplicative update (as defined in subparagraph (d)(4) of this section).

(3) *Annual percentage trend.* The annual percentage trend for a given year is the ratio of the CPI in the previous year (numerator) to the CPI 2 years prior to the given year (denominator).

(4) *Multiplicative update.* The multiplicative update for a given year is the ratio of the product of the annual percentage trends for all prior recorded years, as revised and updated with the most recent available data (numerator) to the product of the annual percentage trends in prior recorded years as published in the previous year's rate announcement (denominator).

* * * * *

■ 50. Section 423.882 is amended by revising the definition of Gross Covered Retiree Plan-Related Prescription Drug Costs and Allowable Retiree Costs to read as follows:

§ 423.882 Definitions.

* * * * *

Allowable retiree costs means the subset of gross covered retiree plan-related prescription drug costs actually paid by the sponsor of the qualified retiree prescription drug plan or by (or on behalf of) a qualifying covered retiree under the plan and the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined by § 423.100 of this part) paid by manufacturers under the Manufacturer Discount Program (as defined by § 423.100 of this part).

* * * * *

Gross covered retiree plan-related prescription drug costs, or gross retiree

costs, means those Part D drug costs incurred under a qualified retiree prescription drug plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of prices paid by the qualified retiree prescription drug plan that is received as reimbursement by the pharmacy or by an intermediary contracting organization, and reimbursement paid to indemnify a qualifying covered retiree when the reimbursement is associated with a qualifying covered retiree obtaining Part D drugs under the qualified retiree prescription drug plan.

(2) All amounts paid under the qualified retiree prescription drug plan by or on behalf of a qualified covered retiree (such as the deductible, coinsurance, cost sharing, or, for years prior to 2025, amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the qualified retiree prescription drug plan.

(3) All amounts paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100 of this part).

* * * * *

§ 423.884 [Amended]

■ 51. Section 423.884 is amended by—

■ a. In paragraph (c)(2)(v)(D) by removing the word “Gender” and adding in its place the word “Sex.”

■ b. In paragraphs (d), (d)(1)(i), (d)(1)(ii), and (d)(5)(iii)(C) by removing the phrase “not taking into account the value of any discount or coverage provided during the coverage gap” and replacing it with the phrase “for years prior to 2025, not taking into account the value of any discount or coverage provided during the coverage gap and for 2025 and subsequent years, not taking into account the value of any discount provided under the Manufacturer Discount Program.”

■ 52. Section 423.1000 is amended by revising paragraph (a)(3) to read as follows:

§ 423.1000 Basis and scope.

(a) * * *

(3)(i) CMS must impose a civil money penalty on a manufacturer that fails to provide applicable discounts for applicable drugs of the manufacturer dispensed to applicable beneficiaries in accordance with the terms of such manufacturer's—

(A) Coverage Gap Discount Program agreement, in accordance with section 1860D–14A(e)(2) of the Act; and

(B) Manufacturer Discount Program agreement, in accordance with section 1860D–14C(e) of the Act.

(ii) The provisions of section 1128A (other than subsections (a) and (b)) of the Act apply to a civil money penalty under paragraph (a)(3)(i) of this section.

■ 53. Section 423.1002 is amended by ■ a. Revising the definition of “Affected party”.

The revision reads as follows:

§ 423.1002 Definitions

* * * * *

Affected party means any Part D sponsor or, for purposes of the Coverage Gap Discount Program, any manufacturer (as defined in § 423.100), or, for purposes of the Manufacturer Discount Program, any manufacturer that is an agreement holder (as defined in § 423.2704), impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and “party” means the affected party or CMS, as appropriate.

* * * * *

■ 54. Section 423.2261 is amended by adding paragraph (a)(3) to read as follows:

§ 423.2261 Submission, review, and distribution of materials.

(a) * * *

(3)(i) Part D sponsors offering dual eligible special needs plans with exclusively aligned enrollment subject to § 422.107(e) must submit all materials for the contract in HPMS under the Part D sponsor's contract number.

(ii) Part D sponsors and third-party marketing organizations may not submit materials for the contract under the organization's Multi-Contract Entity number as described in § 423.2262(d)(2)(i).

* * * * *

§ 423.2262 [Amended]

■ 55. Section 423.2262 is amended by removing paragraphs (a)(1)(i) and (ii) and redesignating paragraphs (a)(1)(iii) through (xviii) as (a)(1)(i) through (xvi), respectively.

■ 56. Section 423.2264 is amended by—

■ a. In paragraph (c)(1)(ii)(D), removing the phrase “Cards, but not including Scope” and adding in its place “Cards and Scope”; and

■ b. Revising paragraphs (c)(2)(i), (c)(3) introductory text, and (c)(3)(i).

The revisions read as follows:

§ 423.2264 Beneficiary contact.

* * * * *

(c) * * *

(2) * * *

(i) If a marketing event directly follows an educational event, the

beneficiary must be notified that the educational event is ending and a marketing event will begin shortly and be given a sufficient opportunity to leave the educational event prior to the start of the marketing event.

* * * * *

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple) for purposes of discussing marketing topics. Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment, the Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies). The Scope of Appointment must be in writing for in-person personal marketing appointments.

* * * * *

■ 57. Section 423.2267 is amended by—

■ a. Revising paragraph (e)(5)(ii)(A)(2);

■ b. Removing and reserving paragraph (e)(33); and

■ c. Revising paragraphs (e)(41) introductory text and (e)(41)(ii).

The revisions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(5) * * *

(ii) * * *

(A) * * *

(2) Deductible; the initial coverage phase; coverage gap for a year preceding 2025; and catastrophic coverage.

* * * * *

(33) [Reserved]

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all Part D sponsors in the service area the disclaimer consists of the statement: “We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov* or 1–800–MEDICARE to get information on all of your options.” If the TPMO sells for all Part D sponsors in the service area the disclaimer consists of the statement: “Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov* or 1–800–MEDICARE for help with plan choices.” The Part D sponsor must ensure that the disclaimer is as follows:

* * * * *

(ii) Verbally conveyed during sales calls prior to the discussion of any benefits.

* * * * *

■ 58. Section 423.2274 is amended by—

■ a. In paragraph (b)(3), removing the phrase “prior to meeting with potential enrollees” and adding in its place “prior to a personal marketing appointment”; and

■ b. Revising paragraphs (c)(9) and (g)(2)(ii).

The revisions read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(9) Establish and maintain a system for confirming all of the following:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all personal marketing appointments (including telephonic and walk-in).

* * * * *

(g) * * *

(2) * * *

(ii) Record and retain for 6 years all marketing and sales calls, including the audio portion of calls via web-based technology, in their entirety.

■ 59. Section 423.2300 is amended by revising and republishing the section to read as follows:

§ 423.2300 Scope.

(a) *Scope.* This subpart sets forth the requirements for the Medicare coverage gap discount program based on provisions included in sections 1860D–14A and 1860D–43 of the Act, as follows:

(1) Condition for coverage of applicable drugs under Part D.

(2) The Medicare Coverage Gap Discount Program Agreement.

(3) Coverage gap discount payment processes for Part D sponsors.

(4) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(5) Manufacturer audit and dispute resolution processes.

(7) Resolution of beneficiary disputes involving coverage gap discounts.

(8) Compliance monitoring and civil money penalties.

(8) The termination of the Medicare Coverage Gap Discount Program Agreement.

(b) *Applicability.* The requirements of this subpart apply before January 1, 2025, and, with respect to applicable drugs dispensed prior to such date, continue to apply on and after January 1, 2025.

■ 60. Section 423.2305 is amended by—

■ a. Revising and republishing the introductory text;

■ b. Revising and republishing the definition of “Applicable discount”;

■ c. Revising and republishing the definition of “Negotiated price”; and

■ d. Removing the definitions of “Applicable number of calendar days”; “Date of dispensing”; “Labeler code”; “Manufacturer”; “Medicare Coverage Gap Discount Program”; “Medicare Coverage Gap Discount Program Agreement”; “National Drug Code”; and “Third Party Administrator”.

The revisions read as follows:

§ 423.2305 Definitions.

As used in this subpart and for purposes of the Coverage Gap Discount Program, unless otherwise specified—

Applicable discount means, with respect to a plan year before 2019, 50 percent or, with respect to plan year 2019 through plan year 2024, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

* * * * *

Negotiated price for purposes of the Coverage Gap Discount Program, means the price for a covered Part D drug that—

* * * * *

§ 423.2310 [Amended]

■ 61. Section 423.2310 is amended in paragraph (a)(1) by removing the phrase “Discount Program” and adding in its place the phrase “Coverage Gap Discount Program”.

■ 62. Section 423.2315 is amended by—

■ a. In paragraph (a), removing the phrase “Program Agreement (or Discount Program Agreement)” and adding in its place the phrase “Program Agreement”;

■ b. In paragraphs (b)(5) and (11), removing the phrase “Discount Program” and adding in its place the phrase “Coverage Gap Discount Program”;

■ c. In paragraph (c)(1), removing the phrase “Discount Program Agreement” and adding in its place the phrase “Coverage Gap Discount Program Agreement” each time it appears;

■ d. Revising paragraph (c)(2); and

■ e. In paragraph (c)(3), removing the phrase “Discount Program Agreement” and adding in its place the phrase “Coverage Gap Discount Program Agreement”;

The revision reads as follows:

§ 423.2315 Medicare Coverage Gap Discount Program Agreement.

* * * * *

(c) * * *

(2) For 2012 and subsequent years prior to 2025, for a Coverage Gap Discount Program Agreement to be effective for a year, a manufacturer must enter into such Agreement not later than January 30th of the preceding year.

* * * * *

§ 423.2320 [Amended]

■ 63. Section 423.2320 is amended in paragraph (b) by removing the phrase “Discount Program” and adding in its place the phrase “Coverage Gap Discount Program”.

§ 423.2330 [Amended]

■ 64. Section 423.2330 is amended in paragraphs (a)(1) and (b)(3) by removing the phrase “Discount Program” and adding in its place the phrase “Coverage Gap Discount Program”.

§ 423.2335 [Amended]

■ 65. Section 423.2335 is amended by removing the phrase “Discount Program” and adding in its place the phrase “Coverage Gap Discount Program”;

§ 423.2340 [Amended]

■ 66. Section 423.2340 is amended in paragraphs (a), (b), (c) introductory text, and (c)(1) by removing the phrase “Discount Program Agreement” and adding in its place the phrase “Coverage Gap Discount Program Agreement”;

■ 67. Section 423.2345 is amended by—

■ a. In the section heading, removing the phrase “Discount Program Agreement” and adding in its place the phrase “Coverage Gap Discount Program Agreement”;

■ b. In paragraph (a)(1)—

(i) Removing the phrase “Discount Program Agreement” and adding in its place the phrase “Coverage Gap Discount Program Agreement”; and

(ii) Removing the phrase “Discount Program” and adding in its place the phrase “Coverage Gap Discount Program”;

c. In paragraphs (a)(3)(i), (b)(1), (d), and (e) by removing the phrase “Discount Program Agreement” and adding in its place the phrase “Coverage Gap Discount Program Agreement”; and

■ d. Adding paragraph (f).

The addition reads as follows:

§ 423.2345 Termination of Coverage Gap Discount Program Agreement.

* * * * *

(f) Subject to § 423.2300(b) of this subpart, all Coverage Gap Discount Program Agreements under this subpart are terminated as of January 1, 2025.

■ 68. Section 423.2420 is amended by adding paragraphs (b)(4)(iii) through (v) to read as follows:

§ 423.2420 Calculation of medical loss ratio.

* * * * *

(b) * * *

(4) * * *

(iii) Prospective Manufacturer Discount Program Payments.

(iv) Selected Drug Subsidy Program Payments.

(v) Inflation Reduction Act Subsidy Amounts.

* * * * *

■ 69. Section 423.2536 is amended by adding paragraph (m) to read as follows:

§ 423.2536 Waiver of Part D program requirements.

* * * * *

(m) *Provision of specific information.* Section 423.128(d)(1)(i)(A).

■ 70. The heading for Subpart Z is revised to read as follows:

Subpart Z—Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits

* * * * *

■ 71. Section 423.2600 is revised to read as follows:

§ 423.2600 Payment appeals.

Medicare Part D plan sponsors may appeal program integrity prescription drug event record review audit determinations.

(a) *Issues eligible for appeal.*

(1) CMS’s application of Part D policy(ies).

(2) Factual or data errors.

(b) *Issues ineligible for appeal.*

(1) The Part D plan sponsor’s failure to submit documentation in the timeframes specified by CMS during the audit.

(2) The program integrity prescription drug event record review audit methodology.

■ 72. Section 423.2605 is amended by—

■ a. In paragraph (a), removing the phrase “demand letter” and adding in its place the phrase “close out letter”; and

■ b. Revising paragraph (e).

The revision reads as follows:

§ 423.2605 Request for reconsideration.

* * * * *

(e) *Notification of decision.* The independent reviewer decides the reconsideration within 60 calendar days after the timeframe for filing a rebuttal has expired, and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.

* * * * *

■ 73. Section 423.2610 is amended by—

■ a. In paragraph (d)(2)(i), removing the phrase “The Part D RAC” and adding in its place the phrase “The CMS”;

■ b. In paragraph (d)(3) removing the phrase “nor CMS may submit” and adding in its place the phrase “nor CMS is permitted to submit”;

■ c. In paragraph (e), removing the phrase “60 days” and adding in its place the phrase “60 calendar days after the timeframe for filing a rebuttal has expired”;

■ d. Revising paragraph (f).

The revision reads as follows:

§ 423.2610 Hearing official review.

* * * * *

(f) *Effect of hearing official decision.*

The hearing official’s decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 423.2615.

* * * * *

■ 74. Section 423.2615 is amended by—

■ a. In paragraph (b)(2), removing the phrase “nor CMS may submit” and adding in its place the phrase “nor CMS is permitted to submit”;

■ b. In paragraph (d), removing the phrase “45 days” and adding in its place “30 calendar days”;

■ c. Revising paragraph (e).

The revision reads as follows:

§ 423.2615 Review by the Administrator.

* * * * *

(e) *Administrator Review.* If the CMS Administrator agrees to review the hearing official’s decision, he or she determines, after reviewing the hearing record, and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and to CMS within 45 calendar days after the timeframe for filing a rebuttal has expired.

■ 75. Part 423 is amended by adding subpart AA to read as follows:

Sec.

423.2700 Basis and scope.

423.2704 Definitions.

423.2708 Conditions for coverage of drugs under Part D.

423.2712 Applicable discounts.

423.2716 Phase-in of applicable discount for certain manufacturers.

423.2720 Determination of phase-in eligibility.

423.2724 Effect of manufacturer acquisition on phase-in eligibility.

423.2728 Recalculation of phase-in eligibility determination.

423.2732 Use of third party administrator.

- 423.2736 Requirement for point-of-sale discounts.
- 423.2740 Negative invoice payment process for Part D sponsors.
- 423.2744 Prospective payments to Part D sponsors.
- 423.2748 Requirement to use the Health Plan Management System.
- 423.2752 Manufacturer Discount Program agreement.
- 423.2756 Manufacturer requirements.
- 423.2760 Audits.
- 423.2764 Dispute resolution.
- 423.2768 Civil money penalties.

Subpart AA—Medicare Part D Manufacturer Discount Program

§ 423.2700 Basis and scope.

(a) *Basis.* This subpart implements section 1860D–14C of the Act and provisions included in section 1860D–43 of the Act.

(b) *Scope.* This subpart sets forth the requirements of the Medicare Part D Manufacturer Discount Program, which requires manufacturers to pay discounts for brand-name drugs and biological products when dispensed to Part D enrollees in the initial and catastrophic coverage phases of the Part D benefit, under the terms of an agreement with CMS, in order for such drugs to be coverable under Part D.

§ 423.2704 Definitions.

As used in this subpart and for purposes of the Manufacturer Discount Program, unless otherwise specified—

Agreement holder means a manufacturer that has executed and has in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

Applicable discount has the meaning set forth at § 423.2712.

Applicable LIS percent has the meaning set forth at § 423.2712(d)(1).

Applicable small manufacturer percent has the meaning set forth at § 423.2712(d)(2).

Covered Part D drug has the meaning set forth at § 423.100.

Dispute submission deadline means the date that is 60 calendar days from the date of the invoice containing the information that is the subject of the agreement holder's dispute.

Negotiated price has the meaning set forth at § 423.100, and with respect to an applicable drug under the Manufacturer Discount Program, such negotiated price includes any dispensing fee and, if applicable, any vaccine administration fee and sales tax.

Network pharmacy has the meaning set forth at § 423.100.

Part D drug has the meaning set forth at § 423.100.

Primary manufacturer has the meaning given such term pursuant to

applicable regulations and guidance for the Medicare Drug Price Negotiation Program.

Specified drug means, with respect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified manufacturer.

Specified small manufacturer drug means, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified small manufacturer.

Total expenditures means with respect to—

(1) Part D, the total gross covered prescription drug costs, as defined in § 423.308; and

(2) Part B, the total Medicare allowed amount (*i.e.*, total allowed charges), inclusive of beneficiary cost sharing, for Part B drugs and biologicals, except that expenditures for a drug or biological that are bundled or packaged into the payment for another service are excluded.

§ 423.2708 Conditions for coverage of drugs under Part D.

(a) *General rule.* Except as specified in paragraph (c) of this section, in order for coverage to be available under Part D for a Part D drug of a manufacturer that is an applicable drug or a selected drug during a price applicability period—

(1) The FDA-assigned labeler code of such applicable drug or selected drug must be covered by a Manufacturer Discount Program agreement (described at § 423.2752) that is in effect;

(2) The manufacturer must participate in the Manufacturer Discount Program in accordance with paragraph (b) of this section; and

(3) The manufacturer must have entered into and have in effect a Manufacturer Discount Program agreement in accordance with paragraph (b) of this section.

(b) *Participation in the Manufacturer Discount Program.* A manufacturer is considered to participate in the Manufacturer Discount Program and to have entered into and have in effect a Manufacturer Discount Program agreement for the purposes of paragraph (a) of this section if the manufacturer does either of the following:

(1) Executes and has in effect its own Manufacturer Discount Program agreement.

(2) Participates in the Manufacturer Discount Program by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement that is in effect.

(c) *Exception.* Paragraph (a) of this section does not apply to an applicable drug that is not covered by a Manufacturer Discount Program agreement if CMS has made a determination that the availability of the drug is essential to the health of Part D enrollees. This exception to the general rule in paragraph (a) of this section does not apply to any applicable drug or selected drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to such manufacturer.

(d) *Non-applicable drugs.* Coverage under Part D is available for non-applicable drugs (as defined at § 423.100) of a manufacturer regardless of whether the manufacturer participates in the Manufacturer Discount Program or has a Manufacturer Discount Program agreement in effect.

§ 423.2712 Applicable discounts.

(a) *Defined.* For purposes of the Manufacturer Discount Program, applicable discount means, subject to the requirements of this section, with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary who has—

(1) Not incurred costs, as defined at § 423.100, for covered Part D drugs (as defined at § 423.100) in the year that are equal to or exceed the annual out-of-pocket threshold specified at § 423.104(d)(5)(iii) for the year, 10 percent of the negotiated price of such drug; and

(2) Incurred costs, as defined in § 423.100, for covered Part D drugs (as defined at § 423.100) in the year that are equal to or exceed the annual out-of-pocket threshold specified at § 423.104(d)(5)(iii) for the year, 20 percent of the negotiated price of such drug.

(b) *Application of supplemental benefits.* For Part D plans offering supplemental benefits (as defined in § 423.100), the value of any applicable discount under the Manufacturer Discount Program is calculated before the application of supplemental benefits.

(c) *Application of other coverage.* The applicable discount is calculated before any coverage or financial assistance under another health or prescription drug benefit plan or program that provides prescription drug coverage or financial assistance.

(d) *Application of discount phase-in for specified manufacturers and specified small manufacturers.*

(1) *Applicable LIS percent.* For an applicable drug of a specified manufacturer (as described at § 423.2716(a)) that is marketed as of

August 16, 2022 (as described in paragraph (d)(3) of this section) and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3) of the Act), the applicable discount is as follows:

(i) For the individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- (A) For 2025, 1 percent;
- (B) For 2026, 2 percent;
- (C) For 2027, 5 percent;
- (D) For 2028, 8 percent; and
- (E) For 2029 and each subsequent

year, 10 percent.

(ii) For the individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- (A) For 2025, 1 percent;
- (B) For 2026, 2 percent;
- (C) For 2027, 5 percent;
- (D) For 2028, 8 percent;
- (E) For 2029, 10 percent;
- (F) For 2030, 15 percent; and
- (G) For 2031 and each subsequent

year, 20 percent.

(2) *Applicable small manufacturer percent.* For an applicable drug of a specified small manufacturer (as described at § 423.2716(b)) that is marketed as of August 16, 2022 (as described in paragraph (d)(3) of this section) and dispensed for an applicable beneficiary, the applicable discount is as follows:

(i) For the individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- (A) For 2025, 1 percent;
- (B) For 2026, 2 percent;
- (C) For 2027, 5 percent;
- (D) For 2028, 8 percent; and
- (E) For 2029 and each subsequent

year, 10 percent.

(ii) For the individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

- (A) For 2025, 1 percent;
- (B) For 2026, 2 percent;
- (C) For 2027, 5 percent;
- (D) For 2028, 8 percent;
- (E) For 2029, 10 percent;
- (F) For 2030, 15 percent; and
- (G) For 2031 and each subsequent

year, 20 percent.

(3) An applicable drug of a specified manufacturer or a specified small manufacturer, as applicable, is considered to have been marketed as of August 16, 2022 if the applicable drug had Part D expenditures on or before August 16, 2022, and did not have a marketing end date on the FDA NDC SPL Data Elements File before August 17, 2022.

(e) *Straddle claims.* In the case of a claim for an applicable drug for an applicable beneficiary that straddles multiple phases of the Part D benefit for claims that do not fall entirely—

(1) Above the annual deductible specified at § 423.104(d)(1), the manufacturer provides the applicable discount on only the portion of the negotiated price that falls above the deductible; and

(2) Below or entirely above the annual out-of-pocket threshold specified at § 423.104(d)(5)(iii), the manufacturer provides the applicable discount on each portion of the negotiated price in accordance with this section based on the benefit phase into which each portion of the negotiated price falls.

(f) *Claims not subject to discount.* The following claims involving an applicable drug are not subject to discounts under the Manufacturer Discount Program:

- (1) Medicare Secondary Payer claims.
- (2) Medicaid Subrogation claims.
- (3) Non-standard format coordination of benefits claims.

(4) Manual claims with a service provider identification qualifier of “Other”.

(g) *Impact of applicable discount on enrollee cost sharing.*

(1) Except as specified in paragraph (g)(2) of this section, the applicable discount does not affect the application of the standard 25 percent coinsurance under § 423.104(d)(2) or the application of the copayment amount under § 423.104(d)(5).

(2) If, after the applicable discount is applied to the negotiated price of an applicable drug, the enrollee cost sharing specified under the plan would exceed such negotiated price minus the applicable discount, the enrollee cost sharing is the negotiated price minus the applicable discount.

§ 423.2716 Phase-in of applicable discount for certain manufacturers.

(a) *Specified manufacturer.* Subject to the limitation with respect to manufacturer acquisitions described at § 423.2724, a specified manufacturer is a manufacturer of an applicable drug that, in 2021, had—

(1) A Coverage Gap Discount Program agreement, as described at § 423.2315, in effect in accordance with § 423.2720(a)(1);

(2) Total expenditures for all of its specified drugs (as defined in § 423.2704) covered by a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 represented less than 1.0 percent of total expenditures for all Part D drugs in 2021; and

(3) Total expenditures for all of its specified drugs that are single source drugs and biological products for which payment may be made under Part B in 2021 represented less than 1.0 percent of the total expenditures under Part B for all drugs or biological products in 2021.

(b) *Specified small manufacturer.* Subject to the limitation with respect to manufacturer acquisition described at § 423.2724, a specified small manufacturer is a manufacturer of an applicable drug that, in 2021—

(1) Is a specified manufacturer as described in paragraph (a) of this section; and

(2) The total expenditures under Part D for any one of its specified small manufacturer drugs covered under a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 are equal to or greater than 80 percent of the total expenditures for all its specified small manufacturer drugs covered under Part D in 2021.

(c) *Aggregation rule.* All entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section.

§ 423.2720 Determination of phase-in eligibility.

For each manufacturer with one or more FDA-assigned labeler codes covered by a Manufacturer Discount Program agreement, CMS will determine whether the manufacturer is a specified manufacturer or a specified small manufacturer when the manufacturer executes a Manufacturer Discount Program agreement, or, in the case of a manufacturer whose FDA-assigned labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement, when such labeler code(s) is first added to such agreement. In applying the aggregation rule at § 423.2716(c), CMS will attribute expenditures for a drug to a manufacturer based on the NDC(s) for the drug, as reported on PDE records. Specifically, CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer to whom the labeler code is assigned by the FDA.

(a) *Identification of specified manufacturers.*

(1) A manufacturer is considered to have had a Coverage Gap Discount Program agreement in 2021, as specified at § 423.2716(a)(1), if the manufacturer—

(i) Had a Coverage Gap Discount Program agreement in effect during 2021; or

(ii) Participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) was covered by another manufacturer's Coverage Gap Discount Program agreement in effect during 2021.

(2) *Part D total expenditures.* In calculating the Part D total expenditures for 2021, CMS will include the total expenditures, as defined at § 423.2704, reported on all final action, non-delete PDE records submitted as of June 30, 2022 for all Part D drugs with dates of dispensing in benefit year 2021.

(i) For purposes of calculating each manufacturer's Part D total expenditures for applicable drugs and percent share of Part D total expenditures for 2021, CMS will—

(A) Identify the relevant NDCs attributable to the manufacturer as reported on the PDE record based on the manufacturer's FDA-assigned labeler code extracted from the first 5 digits of each NDC;

(B) Calculate the Part D total expenditures for applicable drugs of the manufacturer by summing the 2021 Part D total expenditures for all relevant NDCs attributable to the manufacturer; and

(C) Divide the 2021 Part D total expenditures for all applicable drugs of the manufacturer by the 2021 Part D total expenditures for all Part D drugs, then multiply by 100 to calculate the manufacturer's percent share.

(ii) If the manufacturer's Part D total expenditures for its applicable drugs are less than 1.0 percent of the 2021 Part D total expenditures, CMS will consider the manufacturer to have satisfied the Part D total expenditure criterion for specified manufacturer phase-in eligibility, specified at § 423.2716(a)(2).

(3) *Part B total expenditures.* In calculating the Part B total expenditures for all drugs and biological products for 2021, CMS will include all Part B Carrier, durable medical equipment (DME), and Outpatient Medicare Part B Fee-for-Service claim line items with a drug- or biological product-related Healthcare Common Procedure Coding System (HCPCS) code submitted as of December 31, 2022.

(i) For purposes of calculating each manufacturer's Part B total expenditures for applicable drugs that are single source drugs and biological products and each manufacturer's percent share of Part B total expenditures for 2021, CMS will—

(A) Map all identified HCPCS codes to NDCs;

(B) Identify all mapped HCPCS codes in paragraph (A) of this paragraph that map to NDCs associated with single source drugs or biological products;

(C) Identify all mapped HCPCS codes identified in paragraph (B) of this paragraph that map only to NDCs associated with single source drugs or biological products of the same manufacturer, consistent with the aggregation rule at § 423.2716(c), based on the manufacturer's FDA-assigned labeler code(s) extracted from the first 5 digits of each NDC;

(D) Attribute 2021 Part B total expenditures for all applicable drugs that are single source drugs or biological products identified in paragraph (C) of this section to each manufacturer, consistent with the aggregation rule at § 423.2716(c), based on the manufacturer's FDA-assigned labeler code(s) extracted from the first 5 digits of each NDC; and

(E) Divide the 2021 Part B total expenditures attributed to each manufacturer in paragraph (D) of this paragraph by the 2021 Part B total expenditures for all drugs and biological products, then multiply by 100 to calculate the manufacturer's percent share.

(ii) If the manufacturer's Part B total expenditures for its applicable drugs that are single source drugs and biologicals are less than 1.0 percent of the 2021 Part B total expenditures, CMS will consider the manufacturer to have satisfied the Part B total expenditure criterion for specified manufacturer phase-in eligibility, specified at § 423.2716(a)(3).

(b) *Identification of specified small manufacturers.*

(1) For each specified manufacturer identified in paragraph (a) of this section, CMS will determine if the 2021 total expenditures under Part D for any one of the manufacturer's specified drugs covered under a Coverage Gap Discount Program agreement for 2021, and covered under Part D in 2021, are equal to or greater than 80 percent of the total expenditures for all of its specified drugs covered under Part D in 2021, as required under § 423.2716(b)(2), as follows.

(i) *Identification of specified small manufacturer drugs.*

(A) For purposes of this section, one specified small manufacturer drug includes—

(1) For drug products, all dosage forms and strengths of a drug with the same active moiety and the same holder of the new drug application (NDA), as described in section 505(c) of the Federal Food, Drug, and Cosmetic Act,

inclusive of products that are marketed under different NDAs.

(2) For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of the biologics license application (BLA), as described in section 351(a) of the Public Health Service Act, inclusive of products that are marketed under different BLAs.

(B) CMS will identify the holder of the NDA or BLA as reported in Drugs@FDA or the FDA Purple Book, respectively.

(C) If a drug is a fixed combination drug, as described in 21 CFR 300.50, with two or more active ingredients or active moieties, the distinct combination of active ingredients or active moieties will be considered one active ingredient or active moiety for the purpose of identifying a specified small manufacturer drug.

(D) CMS will attribute 2021 Part D total expenditures for one specified small manufacturer drug, including authorized generic drugs and repackaged and relabeled drugs, as applicable, to a specified manufacturer based on the NDC(s) for the drug, as reported on PDE records, by matching the labeler code extracted from the first 5 digits of each NDC to the manufacturer to whom the labeler code is assigned by the FDA.

(ii) *Calculation of Part D total expenditures for each drug for 2021.* CMS will calculate the Part D total expenditures for each drug, aggregated in accordance with paragraph (b)(1)(i) of this section, attributable to the manufacturer by summing the Part D total expenditures for all NDCs under each drug as reported on all final action, non-delete PDE records submitted as of June 30, 2022, with dates of dispensing in benefit year 2021.

(iii) *Calculation of each specified drug's percent share of the specified manufacturer's Part D total expenditures for applicable drugs for 2021.* CMS will divide the 2021 Part D total expenditures for each drug, aggregated in accordance with paragraph (b)(1)(i) of this section, by the 2021 Part D total expenditures for all applicable drugs of the manufacturer, as determined under paragraph (a)(2) of this section, then multiply by 100 to determine the percent share.

(iv) If the 2021 Part D total expenditures for one specified drug of the manufacturer are equal to or greater than 80 percent of the manufacturer's 2021 Part D total expenditures for all of its specified drugs, CMS will consider the manufacturer to have satisfied the criterion at § 423.2716(b)(2) for specified small manufacturer phase-in eligibility.

(c) *Written notice of determination.*

(1) CMS will issue a phase-in eligibility determination notice to each manufacturer that has executed and has in effect a Manufacturer Discount Program agreement when such determination is made, delivered by electronic mail, to the primary point of contact as identified by the manufacturer.

(2) In the case of a manufacturer that participates in the Manufacturer Discount Program by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement, CMS will issue a phase-in eligibility determination notice to the agreement holder.

§ 423.2724 Effect of manufacturer acquisition on phase-in eligibility.

For purposes of the Manufacturer Discount Program, when a manufacturer acquires another manufacturer after 2021 (that is, the acquired manufacturer becomes part of such acquiring manufacturer under the aggregation rule at § 423.2716(c)), the acquired manufacturer assumes the phase-in status of the acquiring manufacturer, effective at the beginning of the plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

§ 423.2728 Recalculation of phase-in eligibility determination.

(a) *Right to request a recalculation.* A manufacturer that has received a phase-in eligibility determination notice, as described at § 423.2720(c), may request a recalculation of such determination in accordance with the requirements of this section.

(b) *Timeframe and method of filing.* A manufacturer that seeks a recalculation of its phase-in eligibility determination must file the request, in the manner specified by CMS, no later than 30 calendar days from the date the phase-in eligibility determination notice is electronically sent to the manufacturer. In order to receive consideration, the recalculation request must clearly describe the issue(s) forming the basis of the request and include any relevant supporting information.

(c) *Disposition and notification.* After consideration of the issues raised, CMS will decide whether to perform the recalculation, and will issue a written decision to the manufacturer that will include CMS's decision about whether to perform the requested recalculation and, if such recalculation is performed, the resulting eligibility determination. The decision is final and binding, subject to the requirements of the

Manufacturer Discount Program under section 1860D–14C of the Act, this subpart, and the Manufacturer Discount Program agreement.

(d) *Limitation.* The recalculation process cannot be used to request or be granted an exception to the requirements set forth in statute that determine eligibility for the specified manufacturer or specified small manufacturer phase-in.

§ 423.2732 Use of third party administrator.

(a) CMS will engage a third party administrator (TPA) to assist in the administration of the Manufacturer Discount Program, which may include and is not limited to facilitating—

(1) Manufacturer Discount Program invoicing;

(2) The receipt and distribution of funds of a manufacturer; and

(3) The dispute resolution process described in § 423.2764.

(b) Agreement holders must—

(1) Enter into and have in effect, under the terms and conditions specified by CMS, an agreement with the TPA in order to participate in the Manufacturer Discount Program. The TPA agreement will only terminate upon the termination of the Manufacturer Discount Program agreement; and

(2) Establish and maintain electronic connectivity with the TPA for the purpose of timely transmission of data and funds.

§ 423.2736 Requirement for point-of-sale discounts.

(a) *Point-of-sale discounts.* Part D sponsors must provide applicable discounts on applicable drugs at the point of sale on behalf of the manufacturer. As part of this process, plan sponsors must determine—

(1) Whether an enrollee is an applicable beneficiary as described in § 423.100;

(2) Whether a drug is an applicable drug as described in § 423.100; and

(3) The amount of the discount, in accordance with § 423.2712.

(b) *Direct member reimbursement (DMR).* Part D sponsors must provide applicable discounts on claims for applicable drugs submitted by applicable beneficiaries as DMRs, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan. While the sponsor must account for the discount in adjudicating the DMR request and the associated PDE submitted to CMS, the point-of-sale requirement does not apply.

(c) *Pharmacy prompt payment.* Part D sponsors must reimburse a network

pharmacy (as defined in § 423.100) the amount of the applicable discount within the applicable number of calendar days (as defined in § 423.100) of the date of dispensing (as defined in § 423.100) of an applicable drug, consistent with § 423.520.

(d) *Prescription drug event (PDE) requirements.* Part D sponsors must report the applicable discounts made available to their enrollees under the Manufacturer Discount Program on the PDE records associated with such discounts.

(e) *Retroactive adjustments.* Part D sponsors must make retroactive adjustments to applicable discounts as necessary to reflect applicable changes, including changes to the claim, beneficiary eligibility, or benefit phase determined after the date of dispensing.

§ 423.2740 Negative invoice payment process for Part D sponsors.

(a) CMS will invoice negative amounts to Part D sponsors when a PDE(s) which had been previously invoiced is deleted or adjusted such that the reported Manufacturer Discount Program discount amount is less than originally invoiced.

(b) Part D sponsors are required to pay such negative invoice amounts in the manner specified by CMS within 38 calendar days of receipt of the invoice.

§ 423.2744 Prospective payments to Part D sponsors.

(a) *General rule.* CMS will provide monthly prospective Manufacturer Discount Program payments to Part D sponsors for sponsors to advance manufacturer discounts as specified in § 423.2736(a) and reimburse network pharmacies as specified in § 423.2736(c).

(b) *Exception.* CMS will not provide prospective Manufacturer Discount Program payments to employer group waiver plans.

(c) *Reconciliation.* CMS will reconcile prospective Manufacturer Discount Program payments in accordance with subpart G of this part.

(d) *Manufacturer bankruptcy.* In the event that an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and as a result of such bankruptcy does not pay the invoiced amounts described in § 423.2756(a), CMS will adjust the Manufacturer Discount Program reconciliation amount for affected Part D sponsors to account for the invoiced amounts owed for the contract year being reconciled. The government reserves the right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to

attempt to recover such unpaid amounts and any civil money penalties imposed by CMS under these regulations.

§ 423.2748 Requirement to use the Health Plan Management System.

Agreement holders are required to maintain Health Plan Management System (HPMS) access and use the HPMS to—

(a) Provide and maintain required information, as specified by CMS;

(b) Attest to the completeness and accuracy of data necessary for CMS to determine whether the manufacturer qualifies as a specified manufacturer or specified small manufacturer, as described at § 423.2716;

(c) Execute a Manufacturer Discount Program agreement and a TPA agreement; and

(d) As otherwise specified by CMS to administer the program.

§ 423.2752 Manufacturer Discount Program agreement.

Manufacturers that are agreement holders, as defined in § 423.2704, must comply with all requirements of this section.

(a) *Requirements of agreement.* The manufacturer must:

(1) Reimburse, within the required 38-day timeframe, all applicable discounts invoiced to the manufacturer, consistent with the requirements at § 423.2756(b).

(2) Provide CMS with all labeler codes covered by the agreement.

(3) Ensure that the labeler codes provided to CMS under paragraph (a)(2) of this section include, at a minimum, all labeler codes assigned by the FDA to the manufacturer, in accordance with § 423.2756(c)(3).

(4) Comply with the requirements established by CMS for purposes of administering the Manufacturer Discount Program and monitoring compliance with such program, including providing the manufacturer's Employer Identification Number (EIN) and other identifying information to CMS upon request.

(5) Comply with the requirements related to the provision and maintenance of data at § 423.2756(c).

(6) Enter into and have in effect, under the terms and conditions specified by CMS, an agreement with the TPA, as described at § 423.2732(b)(1), and comply with such agreement and all TPA instructions, processes, and requirements.

(7) Provide and attest to information in the manner and form specified by CMS as necessary for CMS to determine eligibility for and implement the specified manufacturer and specified small manufacturer phase-ins described at § 423.2716.

(8) Agree that, no less than 30 days after the date CMS determines that a primary manufacturer of a selected drug has, in accordance with paragraph (c)(1)(ii) of this section, provided notice to CMS of its decision not to enter into or continue its participation in the Medicare Drug Price Negotiation Program and to discontinue its applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, none of the drugs of such primary manufacturer will be covered by the manufacturer's Manufacturer Discount Program agreement.

(9) Comply with all other requirements of the Manufacturer Discount Program.

(b) *Agreement term and renewal.*

(1) A Manufacturer Discount Program agreement described in this section is valid for an initial term of not less than 12 months and automatically renews for a period of 1 year on each subsequent January 1, except as described in paragraph (b)(3) this section, unless terminated in accordance with paragraph (c) of this section.

(2) For calendar year 2025, an agreement holder must enter into such agreement no later than March 1, 2024, and the initial 12-month term of such agreement begins on January 1, 2025 and ends on December 31, 2025.

(3) For calendar year 2026 and subsequent years, a Manufacturer Discount Program agreement will become effective on the first day of a calendar quarter as follows:

(i) An agreement holder must enter into the agreement no later than the last day of the first month of a calendar quarter in order for the agreement to be effective on the first day of the next calendar quarter.

(ii) If an agreement holder enters into the agreement after the last day of the first month of a particular calendar quarter, the agreement becomes effective on the first day of the second calendar quarter after the calendar quarter in which the manufacturer entered into the agreement.

(iii) An initial term that begins on January 1 will end on December 31 of the same calendar year. An initial term that begins on April 1, July 1, or October 1 will end on December 31 of the following calendar year.

(c) *Termination of Manufacturer Discount Program agreement.*

(1) *Termination by CMS.*

(i) CMS may terminate a Manufacturer Discount Program agreement for a knowing and willful violation of the requirements of such agreement or other good cause shown in relation to a manufacturer's participation in the

Manufacturer Discount Program, including good cause as set forth in paragraph (c)(1)(ii) of this section.

(ii) CMS may terminate a Manufacturer Discount Program agreement for good cause, in the case of a primary manufacturer under the Medicare Drug Price Negotiation Program, upon submission of a request from such manufacturer to terminate its applicable agreements under the Manufacturer Discount Program in connection with a notice of the primary manufacturer's decision that it is unwilling to participate in, or continue its participation in, the Medicare Drug Price Negotiation Program. If CMS determines such a notice complies with all requirements set forth in applicable regulations and guidance for the Medicare Drug Price Negotiation Program, the primary manufacturer's request will constitute good cause under paragraph (c)(1) of this section to terminate the primary manufacturer's applicable agreements under the Manufacturer Discount Program. The primary manufacturer's applicable agreements include any Manufacturer Discount Program agreement for which the primary manufacturer is the agreement holder, as well as any arrangement under § 423.2708(b)(2) in which FDA-assigned labeler codes of the primary manufacturer are covered under the Manufacturer Discount Program agreement of another manufacturer. If applicable, CMS will effectuate termination of coverage of such FDA-assigned labeler codes of the primary manufacturer that are covered under the Manufacturer Discount Program agreement of another manufacturer in accordance with paragraph (c)(1)(v)(A)(1) of this section.

(iii) Any termination by CMS must not be effective earlier than 30 days from the date of the notice to the manufacturer of such termination. If a hearing is timely requested by the manufacturer in accordance with paragraph (c)(1)(iv) of this section, such termination must not be effective prior to resolution of timely appeal requests received in accordance with the requirements of this section.

(iv) CMS will provide, upon written request, a manufacturer a hearing concerning a termination by CMS as follows:

(A) This hearing will take place prior to the effective date of the termination with sufficient time for the termination to be repealed prior to the effective date if CMS determines repeal would be appropriate. If a manufacturer or CMS receives an unfavorable decision from the hearing officer, the manufacturer or CMS may request review by the CMS

Administrator within 30 calendar days of receipt of the notification of such determination. The decision of the CMS Administrator is final and binding.

(B) A timely request for a hearing before a hearing officer or review by the CMS Administrator will stay termination until the parties have exhausted their appeal rights under the Manufacturer Discount Program, which means either the timeframes to pursue a hearing before a hearing officer or review by the CMS Administrator have passed or a final decision by the Administrator has been issued and there is no remaining opportunity to request further administrative review.

(C) In the case of a termination by CMS under paragraph (c)(1)(ii) with respect to a primary manufacturer under the Medicare Drug Price Negotiation Program, the hearing will be held solely on the papers. The only question to be decided in such hearing is whether the primary manufacturer has asked to rescind its request to terminate under paragraph (c)(1)(ii) prior to the effective date of the termination. If so, CMS will automatically grant such request from the primary manufacturer to rescind its request to terminate under paragraph (c)(1)(ii).

(v) In addition to the termination under paragraph (c)(1)(ii) of this section of any Manufacturer Discount Program agreement for which the primary manufacturer is the agreement holder, CMS will effectuate the removal of labeler code(s) that are covered under the Manufacturer Discount Program agreement of another manufacturer and termination of coverage of any specific NDC(s) of applicable drugs and selected drugs of a primary manufacturer that are covered under the Manufacturer Discount Program agreement of another manufacturer as follows:

(A) If a primary manufacturer provides notice to CMS that it is unwilling to participate in, or continue its participation in, the Medicare Drug Price Negotiation Program, consistent with paragraph (c)(1)(ii) of this section, no earlier than 30 days from the date CMS sends the notice of termination to the manufacturer in accordance with paragraph (c)(1)(iii) of this section, CMS will effectuate—

(1) The removal of the FDA-assigned labeler code(s) of the primary manufacturer from any Manufacturer Discount Program agreement of another manufacturer whereby such labeler codes of the primary manufacturer are covered in accordance with § 423.2708(b)(2); and

(2) The termination of coverage under any Manufacturer Discount Program agreement specific to NDCs of

applicable drugs and selected drugs for which the primary manufacturer is the holder of the new drug application or biologics license application. Such termination of coverage will apply to all applicable drug and selected drug NDCs of the primary manufacturer for which the labeler code is assigned to a manufacturer other than the primary manufacturer and for which the primary manufacturer is the new drug application or biologics license application holder for such drug.

(B) The removal of labeler code(s) in accordance with paragraph (c)(1)(v)(A)(1) of this section and the termination of coverage specific to NDCs in accordance with paragraph (c)(1)(v)(A)(2) of this section do not affect the agreement holder's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs with such labeler code(s) or such NDCs that were incurred under the agreement before the effective date of removal or termination.

(2) *Termination by the manufacturer.* An agreement holder may terminate its Manufacturer Discount Program agreement for any reason. The effective date of the termination is as follows:

(i) If the agreement holder notifies CMS of its intent to terminate before January 31 of a calendar year, January 1 of the succeeding calendar year.

(ii) If the agreement holder notifies CMS of its intent to terminate on or after January 31 of a calendar year, January 1 of the second succeeding calendar year.

(3) *Post-termination obligations.* Termination of a Manufacturer Discount Program agreement under the requirements of this section does not affect the agreement holder's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with labeler code(s) covered by such agreement that were incurred under the agreement prior to the effective date of the termination.

(4) *Reinstatement.* Reinstatement in the Manufacturer Discount Program subsequent to termination is available to a manufacturer only upon payment of any and all outstanding applicable discounts and penalties incurred under any previous Manufacturer Discount Program agreement or Coverage Gap Discount Program agreement. The timing of the reinstatement must be consistent with the requirements at § 423.2752(b).

(d) *Automatic assignment upon change of ownership.* In the event of a change in ownership of a manufacturer that is an agreement holder, the Manufacturer Discount Program agreement is automatically assigned to

the new owner, and all terms and conditions of the agreement remain in effect as to the new owner unless terminated in accordance with requirements at § 423.2752(c). The new agreement holder agrees to be bound by and to perform all the duties and responsibilities under the Manufacturer Discount Program, and assumes all obligations and liabilities of, and all claims incurred against, the prior agreement holder under the Manufacturer Discount Program agreement whether arising before or after the effective date of the change of ownership.

§ 423.2756 Manufacturer requirements.

Manufacturers that are agreement holders, as defined at § 423.2704, must comply with all requirements of this section.

(a) *Manufacturer invoicing.* CMS will—

(1) Calculate the amounts owed for applicable discounts for applicable drugs having NDCs with a labeler code covered by the agreement holder's Manufacturer Discount Program agreement;

(2) Itemize invoices at the NDC level;

(3) Invoice the agreement holder on a quarterly basis, consistent with the published invoicing calendar; and

(4) Invoice manufacturer discount amounts from accepted PDE data for 37 months following the end of the benefit year.

(b) *Requirement for timely payment.*

(1) Agreement holders that are invoiced in accordance with paragraph (a) are required to pay invoiced amounts within 38 calendar days of receipt of the invoice, in the manner specified by CMS, except as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) If an invoice deadline falls on a Saturday, Sunday, or legal holiday, the payment timeframe is extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday.

(3) Agreement holders are not permitted to withhold payment for any invoiced amount, including a disputed amount while a dispute is pending under § 423.2764, except when the basis for the dispute is that the invoiced amount does not correspond to NDCs of labeler codes covered by the agreement holder's Manufacturer Discount Program agreement. If payment is withheld in such an instance, the agreement holder must notify the TPA within 38 calendar days of the manufacturer's receipt of the applicable invoice that payment is being withheld for this reason.

(c) *Reporting requirements.*

(1) *General.* Agreement holders are required to collect, have available, and maintain appropriate data related to the labeler codes covered by their Manufacturer Discount Program agreement, and maintain such data for a period of not less than 10 years from the date of payment of the invoice.

(2) *Manufacturer ownership.*

Agreement holders must—

(i) Provide and attest to ownership and other data, in the form and manner specified by CMS, as necessary for CMS to determine eligibility for and implement the discount phase-ins described at § 423.2716;

(ii) Notify CMS of a change in their ownership no later than 30 calendar days after the agreement holder executes a legal obligation for such an arrangement and no later than 45 calendar days prior to such change in ownership taking effect; and

(iii) If the agreement holder covers the FDA-assigned labeler code(s) of another manufacturer by its Manufacturer Discount Program agreement in accordance with § 423.2708(b)(2), comply with the requirements of paragraphs (c)(2)(i) and (c)(2)(ii) of this section with respect to such other manufacturer.

(3) *Labeler codes.*

(i) An agreement holder is required to cover by its agreement all labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs.

(ii) Consistent with § 423.2708(b)(2), an agreement holder may cover by its Manufacturer Discount Program agreement applicable drugs or selected drugs with labeler code(s) assigned by the FDA to another manufacturer, provided the other manufacturer has not executed and does not have in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

(iii) Agreement holders must provide to CMS:

(A) All labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs, consistent with paragraph (c)(3)(iv) of this section.

(B) All labeler codes assigned by the FDA to another manufacturer that the agreement holder covers by its Manufacturer Discount Program agreement and for which the agreement holder agrees to pay discounts.

(iv) Agreement holders must provide labeler code(s) newly assigned by the FDA to the agreement holder to CMS no later than 3 business days after receiving written notification of the labeler

code(s) from the FDA, and in advance of providing any NDCs associated with such newly assigned labeler codes to electronic database vendors.

(v) Agreement holders must maintain the list of labeler codes covered by their Manufacturer Discount Program agreement, in the manner specified by CMS. Failure to update labeler codes covered by a Manufacturer Discount Program agreement in accordance with the requirements in this section and applicable CMS guidance does not change an agreement holder's obligation to pay invoiced amounts for applicable drugs.

(4) *FDA and related records.*

(i) Agreement holders must:

(A) Ensure that all of their FDA-assigned labeler codes that contain NDCs for any of their applicable drugs or selected drugs are properly listed on the FDA NDC Directory;

(B) Electronically list all NDCs of their applicable drugs or selected drugs with the FDA in advance of commercial distribution of the product(s);

(C) Maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory; and

(D) Maintain up-to-date listings with electronic database vendors to whom they provide their NDCs for pharmacy claims processing.

(ii) If such agreement holder's Manufacturer Discount Program agreement covers labeler code(s) that are assigned by the FDA to another manufacturer that participates in the Manufacturer Discount Program in accordance with § 423.2708(b)(2), the agreement holder must ensure that the requirements of this section are met with respect to such labeler codes.

(d) Agreement holders are permitted to transfer labeler code(s) from one Manufacturer Discount Program agreement to another provided that the transfer is consistent with the requirements of this subpart and the Manufacturer Discount Program agreement and is approved by CMS.

§ 423.2760 Audits.

(a) *Manufacturer audits of TPA data.*

(1) An agreement holder may conduct periodic audits, no more often than annually, of the TPA data and information used to determine discounts for applicable drugs covered by the agreement holder's Manufacturer Discount Program agreement, directly or through third parties.

(2) The agreement holder must provide the TPA with 60 days' notice of the reasonable basis for the audit and a

description of the information required for the audit.

(3) The audit is limited as follows:

(i) The data provided to the agreement holder conducting the audit is limited to a statistically significant random sample of data held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with labeler codes covered by the agreement holder's Manufacturer Discount Program agreement.

(ii) Manufacturers are not permitted to audit CMS records or the records of Part D sponsors beyond the data provided to the TPA, which includes claim-level information.

(iii) Audits must occur on site at a location specified by the TPA and, with the exception of work papers, such data cannot be removed from the audit site.

(iv) The auditor for the agreement holder may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *CMS audits of manufacturers.*

(1) An agreement holder is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS must provide the agreement holder with 60 calendar days' notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to labeler codes covered by the agreement holder's Manufacturer Discount Program agreement and related NDC last lot expiration dates, utilization, and pricing information relied on by the agreement holder to dispute quarterly invoices, and any other data CMS determines necessary to evaluate compliance with the requirements of the Manufacturer Discount Program.

§ 423.2764 Dispute resolution.

(a) *Initial disputes.* Agreement holders may dispute applicable discounts invoiced to such agreement holder under § 423.2756(a).

(1) *Timeframe and method of filing.* Initial disputes must be filed, in the manner specified by CMS, no later than the dispute submission deadline, as defined at § 423.2704. The agreement holder must explain why it believes the invoiced discount amount is in error and must provide supporting evidence that is material, specific, and related to the dispute.

(2) *Timeframe for making a determination.* CMS will issue a written

determination on an initial dispute no later than 60 calendar days from the dispute submission deadline.

(b) *Independent review.* An agreement holder that receives an unfavorable determination from CMS on its initial dispute or has not received a determination within 60 calendar days from the dispute submission deadline, may request review by the independent review entity (IRE) contracted by CMS.

(1) *Timeframe and method of filing.* A request for review by the IRE must be filed, in the manner specified by CMS, no later than the earlier of the following:

(i) Thirty calendar days from the unfavorable determination on the initial dispute.

(ii) Ninety calendar days from the dispute submission deadline, if no determination was made within 60 calendar days of the dispute submission deadline.

(2) *Information considered.* In addition to the information provided by the agreement holder, the IRE considers information received from CMS, the TPA, the Part D sponsor, or other sources. The IRE may request additional information from the agreement holder for the purpose of considering the appeal. Failure to comply with this request for additional information within the timeframe specified may result in the IRE issuing a denial.

(3) *Timeframe for making a decision.* The IRE issues a written decision to the agreement holder and to CMS no later than 90 calendar days from receipt of the request.

(4) *Notice requirements.* The IRE decision must include all of the following:

(i) A clear statement indicating whether the decision is favorable or unfavorable to the agreement holder.

(ii) An explanation of the rationale for the IRE's decision.

(iii) Instructions on how to request a review by the CMS Administrator.

(5) *Effect of IRE decision.* A decision by the IRE is binding on all parties unless the agreement holder or CMS files a valid request for review by the CMS Administrator under the process described in paragraph (c) of this section.

(c) *Review by the CMS Administrator.*

(1) CMS or an agreement holder that receives an unfavorable decision by the IRE may request a review of a determination from the IRE by the CMS Administrator.

(2) A request for review by the CMS Administrator must be filed, in the manner specified by CMS, no later than 30 calendar days from the date of the IRE decision.

(3) The CMS Administrator issues a written decision to both parties.

(4) A decision by the CMS Administrator is final and binding.

(d) *Adjustment to invoiced amounts.* CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary) if the dispute is resolved in favor of the agreement holder.

(e) *Limitation.* The dispute resolution process described in this section must not be used to dispute a decision by CMS to terminate an agreement holder's participation in the Manufacturer Discount Program under § 423.2752(c)(1) or a decision by CMS about a manufacturer's eligibility for discount phase-ins described at § 423.2720.

§ 423.2768 Civil money penalties.

(a) *General rule.* An agreement holder that fails to provide, in accordance with the terms of its Manufacturer Discount Program agreement and the requirements of the Manufacturer Discount Program, applicable discounts for applicable drugs covered by the agreement holder's Manufacturer Discount Program agreement and dispensed to applicable beneficiaries is subject to a civil money penalty for each such failure.

(b) *Notice of non-compliance.* When an agreement holder fails to make a timely payment as required under § 423.2756(b), CMS will issue to the agreement holder a notice of non-compliance with information about the violation. The agreement holder has 5 business days from the date of the notice to respond to CMS.

(c) *Determination of the civil money penalty amounts.* CMS must impose a civil money penalty for each failure equal to the sum of:

(1) The amount an agreement holder would have paid with respect to the applicable discount; and

(2) Twenty-five percent of such amount.

(d) *Notice to impose civil money penalties.* If CMS makes a determination to impose a civil money penalty as set forth in paragraph (c) of this section, CMS will send to the agreement holder a written notice of such determination that includes all of the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The agreement holder's right to a hearing as set forth in paragraph (e) of this section.

(6) Information about where to file the request for a hearing.

(e) *Appeal procedures for civil money penalties.* An agreement holder has a right to a hearing following a decision by CMS to impose a civil money penalty according to the administrative appeal process and procedures established in subpart T of this part.

(f) *Collection.*

(1) CMS may not collect a civil money penalty until the affected party (as defined in § 423.1002) has received notice and the opportunity for a hearing under section 1128A(c)(2) of the Act.

(2) An agreement holder that has received from CMS a notice of determination to impose a civil money penalty must pay such civil money penalty in full within 60 calendar days of the date of the CMS notice of determination, except as provided in paragraph (f)(3) of this section.

(3) If the agreement holder requests a hearing to appeal in accordance with 42 CFR part 423, subpart T, the civil money penalty is due, as applicable, once the administrative process as specified in subpart T has concluded.

(4) CMS will initiate the collection of a civil money penalty owed by an agreement holder either following the expiration of 60 days from the date of the CMS notice of determination to impose a civil money penalty, or if later, the conclusion of the administrative process specified in 42 CFR part 423, subpart T, as applicable.

(g) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(h) *Bankruptcy.* In the event an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and as a result of such bankruptcy, fails to pay the total sum of the civil money penalties imposed, the government reserves the right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to attempt to recover such unpaid amounts and any civil money penalties imposed by CMS under these regulations.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.

[FR Doc. 2025–21456 Filed 11–25–25; 4:15 pm]

BILLING CODE 4120-01-P



FEDERAL REGISTER

Vol. 90

Friday,

No. 227

November 28, 2025

Part III

The President

Executive Order 14362—Designation of Certain Muslim Brotherhood Chapters as Foreign Terrorist Organizations and Specially Designated Global Terrorists

Executive Order 14363—Launching the Genesis Mission

Presidential Documents

Title 3—

The President

Executive Order 14362 of November 24, 2025

Designation of Certain Muslim Brotherhood Chapters as Foreign Terrorist Organizations and Specially Designated Global Terrorists

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Immigration and Nationality Act (8 U.S.C. 1101 *et seq.*) (INA), and the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), it is hereby ordered:

Section 1. Purpose. This order sets in motion a process by which certain chapters or other subdivisions of the Muslim Brotherhood shall be considered for designation as Foreign Terrorist Organizations, consistent with section 219 of the INA (8 U.S.C. 1189) and specially designated global terrorists, consistent with IEEPA (50 U.S.C. 1702), and Executive Order 13224 of September 23, 2001 (Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism), as amended.

The Muslim Brotherhood, founded in Egypt in 1928, has developed into a transnational network with chapters across the Middle East and beyond. Relevant here, its chapters in Lebanon, Jordan, and Egypt engage in or facilitate and support violence and destabilization campaigns that harm their own regions, United States citizens, and United States interests. For example, in the aftermath of the October 7, 2023, attack in Israel, the military wing of the Lebanese chapter of the Muslim Brotherhood joined Hamas, Hezbollah, and Palestinian factions to launch multiple rocket attacks against both civilian and military targets within Israel. A senior leader of the Egyptian chapter of the Muslim Brotherhood, on October 7, 2023, called for violent attacks against United States partners and interests, and Jordanian Muslim Brotherhood leaders have long provided material support to the militant wing of Hamas. Such activities threaten the security of American civilians in the Levant and other parts of the Middle East, as well as the safety and stability of our regional partners.

Sec. 2. Policy. It is the policy of the United States to cooperate with its regional partners to eliminate the capabilities and operations of Muslim Brotherhood chapters designated as foreign terrorist organizations pursuant to section 3 of this order, deprive those chapters of resources, and thereby end any threat such chapters pose to United States nationals or the national security of the United States.

Sec. 3. Implementation. (a) Within 30 days of the date of this order, the Secretary of State and the Secretary of the Treasury, after consultation with the Attorney General and the Director of National Intelligence, shall submit a joint report to the President, through the Assistant to the President for National Security Affairs, concerning the designation of any Muslim Brotherhood chapters or other subdivisions, including those in Lebanon, Jordan, and Egypt, as foreign terrorist organizations consistent with 8 U.S.C. 1189, and specially designated global terrorists consistent with 50 U.S.C. 1702 and Executive Order 13224.

(b) Within 45 days of submitting the report required by subsection (a) of this section, the Secretary of State or the Secretary of the Treasury, as applicable, shall take all appropriate action consistent with 8 U.S.C. 1189 or 50 U.S.C. 1702 and Executive Order 13224, as applicable, with regard to the designation of any Muslim Brotherhood chapters or other

subdivisions described in section 1 of this order as foreign terrorist organizations and specially designated global terrorists.

Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

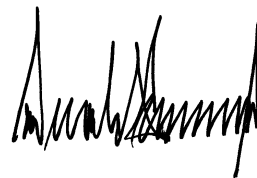
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The costs for publication of this order shall be borne by the Department of State.



THE WHITE HOUSE,
November 24, 2025.

Presidential Documents

Executive Order 14363 of November 24, 2025

Launching the Genesis Mission

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. From the founding of our Republic, scientific discovery and technological innovation have driven American progress and prosperity. Today, America is in a race for global technology dominance in the development of artificial intelligence (AI), an important frontier of scientific discovery and economic growth. To that end, my Administration has taken a number of actions to win that race, including issuing multiple Executive Orders and implementing America's AI Action Plan, which recognizes the need to invest in AI-enabled science to accelerate scientific advancement. In this pivotal moment, the challenges we face require a historic national effort, comparable in urgency and ambition to the Manhattan Project that was instrumental to our victory in World War II and was a critical basis for the foundation of the Department of Energy (DOE) and its national laboratories.

This order launches the "Genesis Mission" as a dedicated, coordinated national effort to unleash a new age of AI-accelerated innovation and discovery that can solve the most challenging problems of this century. The Genesis Mission will build an integrated AI platform to harness Federal scientific datasets—the world's largest collection of such datasets, developed over decades of Federal investments—to train scientific foundation models and create AI agents to test new hypotheses, automate research workflows, and accelerate scientific breakthroughs. The Genesis Mission will bring together our Nation's research and development resources—combining the efforts of brilliant American scientists, including those at our national laboratories, with pioneering American businesses; world-renowned universities; and existing research infrastructure, data repositories, production plants, and national security sites—to achieve dramatic acceleration in AI development and utilization. We will harness for the benefit of our Nation the revolution underway in computing, and build on decades of innovation in semiconductors and high-performance computing. The Genesis Mission will dramatically accelerate scientific discovery, strengthen national security, secure energy dominance, enhance workforce productivity, and multiply the return on taxpayer investment into research and development, thereby furthering America's technological dominance and global strategic leadership.

Sec. 2. Establishment of the Genesis Mission. (a) There is hereby established the Genesis Mission (Mission), a national effort to accelerate the application of AI for transformative scientific discovery focused on pressing national challenges.

(b) The Secretary of Energy (Secretary) shall be responsible for implementing the Mission within DOE, consistent with the provisions of this order, including, as appropriate and authorized by law, setting priorities and ensuring that all DOE resources used for elements of the Mission are integrated into a secure, unified platform. The Secretary may designate a senior political appointee to oversee day-to-day operations of the Mission.

(c) The Assistant to the President for Science and Technology (APST) shall provide general leadership of the Mission, including coordination of

participating executive departments and agencies (agencies) through the National Science and Technology Council (NSTC) and the issuance of guidance to ensure that the Mission is aligned with national objectives.

Sec. 3. *Operation of the American Science and Security Platform.* (a) The Secretary shall establish and operate the American Science and Security Platform (Platform) to serve as the infrastructure for the Mission with the purpose of providing, in an integrated manner and to the maximum extent practicable and consistent with law:

- (i) high-performance computing resources, including DOE national laboratory supercomputers and secure cloud-based AI computing environments, capable of supporting large-scale model training, simulation, and inference;
- (ii) AI modeling and analysis frameworks, including AI agents to explore design spaces, evaluate experimental outcomes, and automate workflows;
- (iii) computational tools, including AI-enabled predictive models, simulation models, and design optimization tools;
- (iv) domain-specific foundation models across the range of scientific domains covered;
- (v) secure access to appropriate datasets, including proprietary, federally curated, and open scientific datasets, in addition to synthetic data generated through DOE computing resources, consistent with applicable law; applicable classification, privacy, and intellectual property protections; and Federal data-access and data-management standards; and
- (vi) experimental and production tools to enable autonomous and AI-augmented experimentation and manufacturing in high-impact domains.

(b) The Secretary shall take necessary steps to ensure that the Platform is operated in a manner that meets security requirements consistent with its national security and competitiveness mission, including applicable classification, supply chain security, and Federal cybersecurity standards and best practices.

(c) Within 90 days of the date of this order, the Secretary shall identify Federal computing, storage, and networking resources available to support the Mission, including both DOE on-premises and cloud-based high-performance computing systems, and resources available through industry partners. The Secretary shall also identify any additional partnerships or infrastructure enhancements that could support the computational foundation for the Platform.

(d) Within 120 days of the date of this order, the Secretary shall:

- (i) identify a set of initial data and model assets for use in the Mission, including digitization, standardization, metadata, and provenance tracking; and
- (ii) develop a plan, with appropriate risk-based cybersecurity measures, for incorporating datasets from federally funded research, other agencies, academic institutions, and approved private-sector partners, as appropriate.

(e) Within 240 days of the date of this order, the Secretary shall review capabilities across the DOE national laboratories and other participating Federal research facilities for robotic laboratories and production facilities with the ability to engage in AI-directed experimentation and manufacturing, including automated and AI-augmented workflows and the related technical and operational standards needed.

(f) Within 270 days of the date of this order, the Secretary shall, consistent with applicable law and subject to available appropriations, seek to demonstrate an initial operating capability of the Platform for at least one of the national science and technology challenges identified pursuant to section 4 of this order.

Sec. 4. *Identification of National Science and Technology Challenges.* (a) Within 60 days of the date of this order, the Secretary shall identify and submit to the APST a detailed list of at least 20 science and technology

challenges of national importance that the Secretary assesses to have potential to be addressed through the Mission and that span priority domains consistent with National Science and Technology Memorandum 2 of September 23, 2025, including:

- (i) advanced manufacturing;
- (ii) biotechnology;
- (iii) critical materials;
- (iv) nuclear fission and fusion energy;
- (v) quantum information science; and
- (vi) semiconductors and microelectronics.

(b) Within 30 days of submission of the list described in subsection (a) of this section, the APST shall review the proposed list and, working with participating agency members of the NSTC, coordinate the development of an expanded list that can serve as the initial set of national science and technology challenges to be addressed by the Mission, including additional challenges proposed by participating agencies through the NSTC, subject to available appropriations.

(c) Following development of the expanded list described in subsection (b) of this section, agencies participating in the Mission shall use the Platform to advance research and development aligned with the national science and technology challenges identified in the expanded list, consistent with applicable law and their respective missions, and subject to available appropriations.

(d) On an annual basis thereafter, the Secretary shall review and update the list of challenges in consultation with the APST and the NSTC to reflect progress achieved, emerging national needs, and alignment with my Administration's research and development priorities.

Sec. 5. *Interagency Coordination and External Engagement.* (a) The APST, through the NSTC, and with support from the Federal Chief Data Officer Council and the Chief AI Officer Council, shall convene relevant and interested agencies to:

- (i) assist participating agencies in aligning, to the extent permitted by law, their AI-related programs, datasets, and research and development activities with the objectives of the Mission in their respective areas of expertise, while avoiding duplication of effort across the Federal Government and promoting interoperability;
- (ii) identify data sources that may support the Mission's aim;
- (iii) develop a process and resourcing plan in coordination with participating agencies for integrating appropriate and available agency data and infrastructure into the Mission, to the extent permitted by law and subject to available appropriations, including methods under which all agencies contributing to the Mission are encouraged to implement appropriate risk-based security measures that reflect cybersecurity best practices;
- (iv) launch coordinated funding opportunities or prize competitions across participating agencies, to the extent permitted by law and subject to available appropriations, to incentivize private-sector participation in AI-driven scientific research aligned with Mission objectives; and
- (v) establish mechanisms to coordinate research and development funding opportunities and experimental resources across participating agencies, ensuring agencies can participate effectively in the Mission.

(b) The APST shall coordinate with relevant agencies in establishing, consistent with existing authorizing statutes and subject to available appropriations, competitive programs for research fellowships, internships, and apprenticeships focused on the application of AI to scientific domains identified as national challenges for the Mission, to include placement of program participants at DOE national laboratories and other participating Federal

research facilities, with the purpose of providing access to the Platform and training in AI-enabled scientific discovery.

(c) The Secretary, in coordination with the APST and the Special Advisor for AI and Crypto, shall establish mechanisms for agency collaboration with external partners possessing advanced AI, data, or computing capabilities or scientific domain expertise, including through cooperative research and development agreements, user facility partnerships, or other appropriate arrangements with external entities to support and enhance the activities of the Mission, and shall ensure that such partnerships are structured to preserve the security of Federal research assets and maximize public benefit. To facilitate these collaborations, the Secretary shall:

(i) develop standardized partnership frameworks, including cooperative research and development or other appropriate agreements, and data-use and model-sharing agreements;

(ii) establish clear policies for ownership, licensing, trade-secret protections, and commercialization of intellectual property developed under the Mission, including innovations arising from AI-directed experiments;

(iii) implement uniform and stringent data access and management processes and cybersecurity standards for non-Federal collaborators accessing datasets, models, and computing environments, including measures requiring compliance with classification, privacy, and export-control requirements, as well as other applicable laws; and

(iv) establish procedures to ensure the highest standards of vetting and authorization of users and collaborators seeking access to the resources of the Mission and associated research activities, including the Platform and associated Federal research resources.

(d) The APST, through the NSTC, shall, to the extent appropriate, identify opportunities for international scientific collaboration to support activities under the Mission.

Sec. 6. *Evaluation and Reporting.* (a) Within 1 year of the date of this order, and on an annual basis thereafter, the Secretary shall submit a report to the President, through the APST and the Director of the Office of Management and Budget, describing:

(i) the Platform's operational status and capabilities;

(ii) progress toward integration across DOE national laboratories and other participating Federal research partners, including shared access to computing resources, data infrastructure, and research facilities;

(iii) the status of user engagement, including participation of student researchers and any related training;

(iv) updates on research efforts and outcomes achieved, including measurable scientific advances, publications, and prototype technologies;

(v) the scope and outcomes of public-private partnerships, including collaborative research projects and any technology transitions or commercialization activities; and

(vi) any identified needs or recommendations for authorities or interagency support to achieve the Mission's objectives.

Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

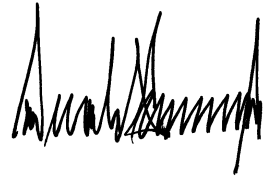
(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party

against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The costs for publication of this order shall be borne by the Department of Energy.

A handwritten signature in black ink, appearing to be a stylized representation of a name, possibly 'Andrew' or similar, with a long horizontal stroke at the end.

THE WHITE HOUSE,
November 24, 2025.

Reader Aids

Federal Register

Vol. 90, No. 227

Friday, November 28, 2025

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, NOVEMBER

49009-49214	3
49215-49246	4
49247-50482	5
50483-50488	6
50489-50740	7
50741-50856	10
50857-50890	12
50891-51016	13
51017-51080	14
51081-51500	17
51501-51988	18
51989-52230	19
52231-52554	20
52555-52846	21
52847-53194	24
53195-54224	25
54225-54522	26
54523-55040	28

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:

10987	49211
10988	51015
10989	51071
10990	51077
10991	51079
10992	52549
10993	54517

Executive Orders:

14357	50725
14358	50729
14359	52227
14360	54091
14361	54467
14362	55033
14363	55035

Administrative Orders:

Memorandums:

Memorandum of November 20, 2025	54223

Notices:

Notice of November 5, 2025	50735
Notice of November 5, 2025	50737
Notice of November 5, 2025	50739
Notice of November 20, 2025	53193

6 CFR

13	49009
139	49247

7 CFR

400	54523
407	54523
457	54523
760	51956, 52231

Proposed Rules:

930	51572

8 CFR

Ch. I	51989
251	51081
258	51081

Proposed Rules:

1	49062
103	49062, 52168
204	49062
207	49062
208	49062
209	49062
210	49062
212	49062, 52168
214	49062
215	49062
216	49062
235	49062
236	49062

240	49062
244	49062
245	49062
245a	49062
264	49062
287	49062
333	49062
335	49062

10 CFR

2	54225
14	54225
810	52847

Proposed Rules:

821	51208
1703	52893

12 CFR

201	51017
204	51018, 52849
209	52231
328	54544

Proposed Rules:

5	51577
27	51583
30	51587
225	51856, 53238
238	51856, 53238
252	51856, 53238
1002	50901, 50952

13 CFR

301	51991

14 CFR

39	49215, 49248, 49251, 51019, 51091, 51094, 51501, 51504, 52232, 52234, 52555, 52558, 52560, 52851, 53195, 53197, 53200, 53203, 53206, 53208, 53210, 53215, 54545, 54549, 54552, 54555, 54559, 54563, 54568
71	51097, 51507, 54228
73	51098
97	50891, 50893

Proposed Rules:

27	52569
39	51212, 51216, 51218, 51222, 51225, 51227, 51590, 51592, 51596, 51600, 51602, 51605, 51607, 51610, 51613, 51620, 52005, 52008, 52264, 52570, 52573, 52897, 52899, 53238, 53243, 53245, 54591, 54593, 54596, 54599, 54601
71	52011, 52576, 52578, 52580, 52899, 52901, 53248
Ch. II	51230

15 CFR

732	50857

734.....50857
 736.....50857
 744.....50857, 50858
 748.....50857

18 CFR**Proposed Rules:**

1.....53249
 35.....53250
 153.....53251
 157.....53250
 254.....53250
 284.....52012
 342.....52902, 53255
 380.....53251

19 CFR

4.....51081
 103.....52796
 122.....51100, 52796

21 CFR

876.....54230
 882.....54232
 1308.....51102

Proposed Rules:

573.....54245
 730.....54603
 866.....53261

22 CFR

126.....50489

23 CFR

660.....51105
 970.....51107
 971.....51109
 973.....51110

24 CFR

570.....51992

25 CFR

559.....54234

26 CFR

1.....53144
 58.....53144

Proposed Rules:

1.....54604

30 CFR

700.....52853, 54571
 816.....54573, 54575
 817.....54575, 54577
 870.....54579
 872.....52855, 52856, 52858,
 52860, 52862
 874.....52862, 54582
 875.....52862, 54583
 879.....52862

885.....52865
 886.....52862
 887.....52862
 935.....51112

Proposed Rules:

917.....51232

31 CFR**Proposed Rules:**

1010.....51234

33 CFR

1.....52867
 26.....52867
 62.....52867
 66.....52867
 67.....52867
 95.....52867
 97.....52867
 100.....52867
 107.....52867
 114.....52867
 115.....52867
 116.....52867
 117.....51508, 52867, 52882
 118.....52867
 133.....52867
 151.....52867
 155.....52867
 159.....52867
 164.....52867
 165.....51510, 52562, 52565,
 52867, 53218
 174.....52867

Proposed Rules:

117.....51623, 54245
 328.....52498

37 CFR

381.....54585

Proposed Rules:

42.....50492

38 CFR

1.....54234

Proposed Rules:

17.....52581

39 CFR

20.....53221, 53225
 111.....50741, 52237, 52883
 601.....51994

Proposed Rules:

111.....52266, 54247
 3050.....49016

40 CFR

52.....50742, 51510, 51512,
 51515, 51518, 51525, 51527,
 51529, 51546, 51548, 51551,
 51554, 51560, 51997, 51999,

52238, 52241, 52242, 52245,
 52248, 52582, 54236, 54586
 62.....54238
 70.....52250
 81.....51548, 51551, 51554,
 51560, 51999

147.....51021
 180.....49254, 51115, 51118,
 51123, 51127, 51164, 51562,
 52252, 52256, 54240
 257.....51168
 272.....51565
 300.....51181
 370.....51187
 423.....54588
 721.....49218
 751.....50894, 51027
 1600.....54242

Proposed Rules:

52.....51029, 51247, 51263,
 52019, 52270, 52288, 52290,
 52297, 52303, 52305, 52308,
 52311, 54248, 54605, 54607,
 54609
 62.....52312, 52313
 63.....52908
 70.....52316, 52318, 54605
 81.....52319
 82.....50766
 84.....51042
 120.....52498
 257.....54611
 271.....51625
 370.....51266
 705.....50923
 721.....49016, 49148, 49180

42 CFR

405.....49266, 54589
 410.....49266, 53448, 54589
 412.....53448
 413.....53068, 53448
 414.....49266, 54589
 415.....53448
 416.....53448
 419.....53448
 424.....49266, 54589
 425.....49266, 54589
 427.....49266, 54589
 428.....49266, 54589
 495.....49266, 54589
 512.....49266, 53068, 54589

Proposed Rules:

422.....54894
 423.....54894

43 CFR

2360.....51470

45 CFR

180.....53448

46 CFR

2.....52867
 3.....52867
 4.....52867
 7.....52867
 11.....52867
 15.....52867
 24.....52867
 26.....52867
 58.....52867
 62.....52867
 68.....52867
 90.....52867
 108.....52867
 110.....52867
 118.....52867
 125.....52867
 126.....52867
 131.....52867
 132.....52867
 133.....52867
 147.....52867
 169.....52867
 177.....52867
 181.....52867
 182.....52867
 188.....52867

47 CFR

2.....53227

Proposed Rules:

1.....54248
 15.....54248
 51.....54266
 73.....51291, 51630, 52327
 74.....52327
 90.....54248

49 CFR**Proposed Rules:**

107.....52348
 385.....52030
 563.....54619
 585.....54619
 1241.....51631
 1251.....51631

50 CFR

218.....50504
 300.....52004
 622.....49014
 648.....50490, 50743, 51570
 660.....51205
 679.....49234, 49235, 49236,
 50483, 52567

Proposed Rules:

17.....51632, 52587, 52592
 622.....52349
 402.....52600
 424.....52607

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion

in today's **List of Public Laws**.

Last List November 24, 2025

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly

enacted public laws. To subscribe, go to https://portalguard.gsa.gov/__layouts/PG/register.aspx.

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.