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Contents

Federal Register

Vol. 88, No. 125

Friday, June 30, 2023

Agriculture Department

See Food Safety and Inspection Service

See Natural Resources Conservation Service

Centers for Medicare & Medicaid Services

PROPOSED RULES

Medicare Program:

End-Stage Renal Disease Prospective Payment System,
Payment for Renal Dialysis Services Furnished to
Individuals with Acute Kidney Injury, etc., 42430–
42544

Children and Families Administration

NOTICES

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

Multistate Financial Institution Data Match with
Federally Assisted State Transmitted Levy, 42370–
42371

Revisions to Recordkeeping to Mitigate the Spread of
COVID-19 in Head Start, 42369–42370

Civil Rights Commission

NOTICES

Meetings:

Florida Advisory Committee, 42288–42289
Georgia Advisory Committee, 42289–42290
Iowa Advisory Committee, 42289

Coast Guard

RULES

Safety Zones:

Annual Fireworks Displays and Other Events in the
Eighth Coast Guard District Requiring Safety Zones:
Madisonville Old Fashioned 4th of July, 42245

Savannah River 4th of July Fireworks Show, Savannah,
GA, 42243–42245

Vineyard Wind 1 Wind Farm Project Area, Outer
Continental Shelf, Lease OCS–A 0501, Offshore
Massachusetts, Atlantic Ocean, 42237–42243

Commerce Department

See Foreign-Trade Zones Board

See Industry and Security Bureau

See International Trade Administration

See National Institute of Standards and Technology

See National Oceanic and Atmospheric Administration

Committee for Purchase From People Who Are Blind or Severely Disabled

NOTICES

Procurement List; Additions and Deletions, 42341–42343

Commodity Futures Trading Commission

NOTICES

Meetings; Sunshine Act, 42343

Community Living Administration

NOTICES

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

State Health Insurance Assistance Program–Senior
Medicare Patrol Survey of Group Outreach and
Education Events, 42371–42372

Copyright Royalty Board

NOTICES

Determination of Adjustment to Administrative Assessment
to Fund Mechanical Licensing Collective, 42396–42397

Corporation for National and Community Service

NOTICES

Privacy Act; Matching Program, 42343–42344

Defense Department

RULES

Privacy Act; Implementation, 42234–42237

NOTICES

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

Prohibition on Contracting with Entities Using Certain
Telecommunications and Video Surveillance
Services or Equipment, 42367–42369

Privacy Act; Systems of Records, 42344–42346

Education Department

NOTICES

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

Revocation of Consent to Share Federal Tax Information
Form, 42347

Meetings:

National Advisory Committee on Institutional Quality
and Integrity, 42347–42349

Employment and Training Administration

NOTICES

Request for Nominations:

Advisory Committee on Apprenticeship, 42394–42395

Energy Department

See Federal Energy Regulatory Commission

See Western Area Power Administration

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 42351

Industry Day—Expanding Clean Energy Generation on DOE
Lands, 42350–42351

Meetings:

Basic Energy Sciences Advisory Committee, 42349–42350
Environmental Management Site-Specific Advisory
Board, Savannah River Site, 42351–42352

Environmental Protection Agency**RULES**

Air Quality State Implementation Plans; Approvals and Promulgations:
 California; Approval, Limited Approval and Limited Disapproval of Air Plan Revisions; Mojave Desert Air Quality Management District; Stationary Source Permits, 42258–42271
 California; Sacramento Metropolitan Air Quality Management District, 42248–42252
 California; Yolo-Solano Air Quality Management District, 42252–42258

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 Chemical Data Reporting under the Toxic Substances Control Act, 42362–42363
 Consolidated Pesticide Registration Submission Portal, 42358–42359
 Environmental Education Local Grants Progress Report Form, 42363–42364
 Importation of On-highway Vehicles and Motorcycles and Nonroad Engines, Vehicles, and Equipment, 42361–42362
 New Source Performance Standards for VOC Emissions from Petroleum Refinery Wastewater Systems, 42360–42361
 Significant New Alternatives Policy Program, 42359–42360
 Environmental Impact Statements; Availability, etc., 42360

Farm Credit Administration**NOTICES**

Meetings; Sunshine Act, 42364

Federal Aviation Administration**RULES**

Airspace Designations and Reporting Points:
 Columbus, MS, 42227–42228
 Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments, 42228–42231

PROPOSED RULES

Airspace Designations and Reporting Points:
 Eastern United States, 42276
 Vicinity of Nottingham, MD, 42276

NOTICES

Airport Property:
 Dona Ana County International Jetport, Santa Teresa, NM; Correction, 42417

Federal Communications Commission**PROPOSED RULES**

All-In Pricing for Cable and Satellite Television Service, 42277–42284
 Petition for Reconsideration of Action in Rulemaking Proceeding, 42276–42277

NOTICES

Privacy Act; Systems of Records, 42364–42367

Federal Election Commission**NOTICES**

Meetings; Sunshine Act, 42367

Federal Energy Regulatory Commission**NOTICES**

Combined Filings, 42352–42355
 Filing:
 THSI bn, LLC, 42352

Federal Motor Carrier Safety Administration**NOTICES**

Exemption Application:
 Qualification of Drivers; Epilepsy and Seizure Disorders, 42417–42420

Fish and Wildlife Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 Northeast Region Alaska Native Handicrafts, 42385–42386
 U.S. Fish and Wildlife Service Concessions, 42382–42385

Food and Drug Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 42374–42375
 Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 Voluntary National Retail Food Regulatory Program Standards, 42372–42374
 Guidance:
 Chronic Rhinosinusitis with Nasal Polyps: Developing Drugs for Treatment, 42375–42376

Food Safety and Inspection Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals
 Accreditation of Laboratories, Transactions and Exemptions, 42286–42287

Foreign-Trade Zones Board**NOTICES**

Application for Expansion under Alternative Site Framework:
 Foreign-Trade Zone 277: Western Maricopa County, AZ (New Magnet Site), 42290

General Services Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment, 42367–42369

Health and Human Services Department

See Centers for Medicare & Medicaid Services
See Children and Families Administration
See Community Living Administration
See Food and Drug Administration
See Indian Health Service
See National Institutes of Health

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 42376–42377
 Request for Information:
 Draft 2023 Framework to Support and Accelerate Smoking Cessation, 42377–42379

Homeland Security Department

See Coast Guard

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 .gov Registrar, 42381–42382

Determination Pursuant to Illegal Immigration Reform and Immigrant Responsibility Act; Rescission, 42381

Indian Affairs Bureau

NOTICES

Indian Gaming:

Extension of Tribal-State Class III Gaming Compact; Middletown Rancheria of Pomo Indians of California and State of California, 42386

Indian Health Service

NOTICES

Performance Review Board Members, 42379

Industry and Security Bureau

NOTICES

Denial of Export Privileges:

Nordwind Airlines, 42290–42292

Meetings:

Sensors and Instrumentation Technical Advisory Committee, 42292

Interior Department

See Fish and Wildlife Service

See Indian Affairs Bureau

See Ocean Energy Management Bureau

Internal Revenue Service

RULES

Additional Guidance on the Transition from Interbank Offer Rates to Other Reference Rates with Respect to the Interest Rates of a Foreign Bank, 42231–42234

NOTICES

Meetings:

Taxpayer Advocacy Panel Joint Committee; Correction, 42427

International Trade Administration

NOTICES

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Brass Rod from India, Israel, and the Republic of Korea, 42300

Certain Aluminum Foil from the People's Republic of China, 42292–42293

Glycine from India, 42298–42300

Low Melt Polyester Staple Fiber from the Republic of Korea, 42300–42302

Multilayered Wood Flooring from the People's Republic of China, 42293–42295

Welded Line Pipe from the Republic of Korea, 42295–42298

Justice Department

NOTICES

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

Annual Progress Report for the Services, Training, Officers, and Prosecutors Formula Grants Program, 42390–42391

Credit Card Payment Form, 42393–42394

Services, Training, Officers, and Prosecutors Formula Grant Program Match Documentation Worksheet, 42391–42392

U.S. Official Order Forms for Schedules I and II Controlled Substances, 42392–42393

Labor Department

See Employment and Training Administration

NOTICES

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

Migrant and Seasonal Farmworker Monitoring Report and Complaint/Apparent Violation Form, 42395–42396

Library of Congress

See Copyright Royalty Board

National Aeronautics and Space Administration

NOTICES

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

Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment, 42367–42369

National Council on Disability

NOTICES

Meetings; Sunshine Act, 42397–42398

National Highway Traffic Safety Administration

NOTICES

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

Automated Vehicle Transparency and Engagement for Safe Testing Initiative, 42421–42424

National Institute of Standards and Technology

NOTICES

Draft Plan for Providing Public Access to the Results of Federally Funded Research, 42302–42303

National Institutes of Health

NOTICES

Meetings:

Center for Scientific Review, 42379–42381

National Institute of Diabetes and Digestive and Kidney Diseases, 42380

National Institute on Drug Abuse, 42381

National Oceanic and Atmospheric Administration

RULES

Atlantic Highly Migratory Species:

Atlantic Bluefin Tuna Fisheries; General Category Retention Limit Adjustment, 42272–42275

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic:

Reef Fish Resources of the Gulf of Mexico and Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; Conversion of Historical Captain Permits, 42271–42272

NOTICES

Meetings:

Council Coordination Committee, 42303–42304

Taking and Importing Marine Mammals:

Marine Site Characterization Surveys in the New York Bight, 42322–42341

Taking or Importing of Marine Mammals:

San Francisco Bay Area Water Emergency Transportation Authority's Ferry Terminal Refurbishment in Alameda, CA, 42304–42322

Natural Resources Conservation Service

NOTICES

Proposed Revisions to the National Handbook of

Conservation Practices for the Natural Resources Conservation Service, 42287–42288

Nuclear Regulatory Commission**NOTICES**

Meetings; Sunshine Act, 42398

Ocean Energy Management Bureau**NOTICES**

Environmental Impact Statements; Availability, etc.:
Proposed Beacon Wind Project on the U.S. Outer
Continental Shelf Offshore Massachusetts, 42386–
42390

Personnel Management Office**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Report of Medical Examination of Person Electing
Survivor Benefits, 42399

Meetings:

Federal Prevailing Rate Advisory Committee, 42398–
42399

Pipeline and Hazardous Materials Safety Administration**PROPOSED RULES**

Pipeline Safety:

Gas Pipeline Leak Detection and Repair, 42284–42285

Postal Service**RULES**

Priority Mail Express Refunds, 42247–42248

NOTICES

Environmental Impact Statements; Availability, etc.:
Next Generation Delivery Vehicles Acquisitions, 42401–
42402

Privacy Act; Systems of Records, 42399–42401

Securities and Exchange Commission**RULES**

Prohibition Against Fraud, Manipulation, or Deception in
Connection with Security-Based Swaps; Prohibition
against Undue Influence over Chief Compliance
Officers, 42546–42585

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 42402–42404

Self-Regulatory Organizations; Proposed Rule Changes:
Financial Industry Regulatory Authority, Inc., 42404–
42409

Nasdaq MRX, LLC, 42409–42414

State Department**NOTICES**

Designation as Foreign Terrorist Organization:
ISIL-Libya and Real IRA (and Other Aliases); Review and
Amendment, 42415

Designation as Specially Designated Global Terrorists
Terrorist or Global Terrorist:
ISIL-Libya and Real IRA (and Other Aliases);
Amendment, 42414–42415

Surface Transportation Board**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Classification Index Survey Form, 42415–42416

Lease and Operation Exemption:

Naugatuck Railroad Co.; Boston and Maine Corp. and
Springfield Terminal Railway Co., 42416

Tennessee Valley Authority**NOTICES**

Environmental Impact Statements; Availability, etc.:
Cheatham County Generation Site, 42416–42417

Transportation Department

See Federal Aviation Administration

See Federal Motor Carrier Safety Administration

See National Highway Traffic Safety Administration

See Pipeline and Hazardous Materials Safety
Administration

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 42424–42427

Treasury Department

See Internal Revenue Service

Veterans Affairs Department**RULES**

Allowances for Caskets and Urns for Unclaimed Remains of
Veterans, 42245–42247

NOTICES

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

Designation of Beneficiary Government Life Insurance
and Supplemental Designation of Beneficiary
Government Life Insurance, 42427–42428

Designation of Beneficiary Government Life Insurance
and Supplemental Designation of Beneficiary
Government Life Insurance; Withdrawal, 42427

Western Area Power Administration**NOTICES**

Rate Order:

Desert Southwest Region, 42355–42358

Separate Parts In This Issue**Part II**

Health and Human Services Department, Centers for
Medicare & Medicaid Services, 42430–42544

Part III

Securities and Exchange Commission, 42546–42585

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.

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electronic mailing list, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your e-mail
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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.

14 CFR

71 42227
97 (2 documents) 42228,
42230

Proposed Rules:

71 (2 documents) 42276

17 CFR

240 42546

26 CFR

1 42231

32 CFR

310 42234

33 CFR

147 42237
165 (2 documents) 42243,
42245

38 CFR

38 42245

39 CFR

111 42247

40 CFR

52 (3 documents) 42248,
42252, 42258

42 CFR**Proposed Rules:**

413 42430
512 42430

47 CFR**Proposed Rules:**

54 42276
76 42277

49 CFR**Proposed Rules:**

191 42284
192 42284
193 42284

50 CFR

622 42271
635 42272

Rules and Regulations

Federal Register

Vol. 88, No. 125

Friday, June 30, 2023

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–1352; Airspace Docket No. 23–ASO–24]

RIN 2120–AA66

Amendment of Class D and Class E Airspace; Columbus, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D airspace, Class E surface airspace, and Class E airspace extending upward from 700 feet above the surface for Golden Triangle Regional Airport, Columbus, MS, by updating the airport's description header and geographic coordinates, as well as the geographic coordinates of Columbus AFB, Columbus-Lowndes County Airport, Oktibbeha Airport, and McCharen Field. In addition, this action makes the editorial changes replacing the term Notice to Airmen with Notice to Air Missions and replacing the term Airport/Facility Directory with Chart Supplement. This action does not change the airspace boundaries or operating requirements.

DATES: Effective 0901 UTC, October 5, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: This final rule may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval helps, and guidelines are available on the website. It is available 24 hours a day, 365 days a year.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed

online at www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it updates airspace descriptions. This update is an administrative change and does not change the airspace boundaries or operating requirements.

Incorporation by Reference

Class D and Class E airspace are published in paragraphs 5000, 6002, and 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 annually. This document amends the current version of that order, FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next FAA Order JO 7400.11 update. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class D airspace, Class E surface airspace, and Class E airspace

extending upward from 700 feet above the surface for Golden Triangle Regional Airport, Columbus, MS, by updating the airport's description header's city name from Columbus Golden Triangle, MS to Columbus, MS in the Class D and Class E surface airspace descriptions, and the airport's geographic coordinates, as well as the geographic coordinates of Columbus AFB, Columbus-Lowndes County Airport, Oktibbeha Airport, and McCharen Field. In addition, this action makes the editorial changes replacing the term Notice to Airmen with Notice to Air Missions and replacing the term Airport/Facility Directory with Chart Supplement in the appropriate descriptions. This action is an administrative change and does not affect the airspace boundaries or operating requirements; therefore, notice and public procedure under 5 U.S.C. 553(b) is unnecessary.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant the preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO MS D Columbus, MS [Amended]

Golden Triangle Regional Airport, MS
(Lat 33°26'54" N, long 88°35'29" W)

That airspace extending upward from the surface to and including 2,800 feet MSL within a 4.1-mile radius of the Golden Triangle Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6002 Class E Surface Airspace.

* * * * *

ASO MS E2 Columbus, MS [Amended]

Golden Triangle Regional Airport, MS
(Lat 33°26'54" N, long 88°35'29" W)

That airspace extending upward from the surface within a 4.1-mile radius of the Golden Triangle Regional Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO MS E5 Columbus, MS [Amended]

Columbus AFB, MS
(Lat 33°38'43" N, long 88°26'45" W)
Monroe County Airport
(Lat 33°52'26" N, long 88°29'23" W)
Columbus-Lowndes County Airport

(Lat 33°27'55" N, long 88°22'51" W)
Golden Triangle Regional Airport
(Lat 33°26'54" N, long 88°35'29" W)
Oktibbeha Airport
(Lat 33°29'52" N, long 88°4'53" W)
McCharen Field
(Lat 33°35'03" N, long 88°40'00" W)

That airspace extending upward from 700 feet above the surface within a 10-mile radius of Columbus AFB, and within a 16-mile radius of Monroe County Airport, and within a 6.4-mile radius of Columbus-Lowndes County Airport, and within a 6.6-mile radius of Golden Triangle Regional Airport, and within a 6.2-mile radius of Oktibbeha Airport, and within a 6.3-mile radius of McCharen Field.

* * * * *

Issued in College Park, Georgia, on June 27, 2023.

Andree C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2023–13912 Filed 6–29–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97**

[Docket No. 31493; Amdt. No. 4066]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective June 30, 2023. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director

of the Federal Register as of June 30, 2023.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, email fr.inspection@nara.gov or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone: (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation

by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and

ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on June 9, 2023.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
13-Jul-23	MO	Lee's Summit	Lee's Summit Muni	3/1625	5/25/23	RNAV (GPS) RWY 11, Amdt 2.
13-Jul-23	MO	Lee's Summit	Lee's Summit Muni	3/1626	5/25/23	RNAV (GPS) RWY 29, Amdt 3.
13-Jul-23	PA	Harrisburg	Capital City	3/1844	5/15/23	RNAV (GPS) RWY 26, Orig-C.
13-Jul-23	OK	Bartlesville	Bartlesville Muni	3/2185	5/25/23	VOR/DME RWY 35, Amdt 6A.
13-Jul-23	AL	Eufaula	Weedon Fld	3/4366	6/1/23	RNAV (GPS) RWY 18, Amdt 1D.
13-Jul-23	AZ	Phoenix	Phoenix Deer Valley	3/4861	5/26/23	RNAV (GPS) RWY 7R, Amdt 1A.
13-Jul-23	AZ	Phoenix	Phoenix Deer Valley	3/4862	5/26/23	RNAV (GPS) RWY 25L, Orig-C.
13-Jul-23	AZ	Phoenix	Phoenix Deer Valley	3/4863	5/26/23	RNAV (GPS)-B, Orig-A.
13-Jul-23	MT	Circle	Circle Town County	3/6404	5/30/23	Takeoff Minimums and Obstacle DP, Orig.

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97**

[Docket No. 31492; Amdt. No. 4065]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective June 30, 2023. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 30, 2023.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590-0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954-1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPs, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, 8260-15B, when required by an entry on 8260-15A, and 8260-15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff

Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on June 9, 2023.

Thomas J. Nichols,

*Aviation Safety, Flight Standards Service,
Manager, Standards Section, Flight
Procedures & Airspace Group, Flight
Technologies & Procedures Division.*

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 13 July 2023

Danbury, CT, KDXR, RNAV (GPS) Z RWY 8,
Orig

Effective 10 August 2023

Phoenix, AZ, KDVT, DEER VALLEY THREE,
Graphic DP

Washington, IN, KDCY, RNAV (GPS) RWY
18, Amdt 2

Washington, IN, KDCY, Takeoff Minimums
and Obstacle DP, Amdt 1

Pinecreek, MN, 48Y, RNAV (GPS) RWY 15,
Orig-C

Andrews, NC, KRHP, RNAV (GPS) RWY 8,
Amdt 2

Andrews, NC, KRHP, Takeoff Minimums and
Obstacle DP, Amdt 2

Goldsboro, NC, KGWW, ILS OR LOC RWY
23, Amdt 2D

Devils Lake, ND, KDVL, ILS OR LOC RWY
31, Amdt 4

Devils Lake, ND, KDVL, RNAV (GPS) RWY
31, Amdt 2

Langdon, ND, D55, RNAV (GPS) RWY 14,
Orig-B

Langdon, ND, D55, RNAV (GPS) RWY 32,
Orig-B

Atlantic City, NJ, KACY, ILS Z OR LOC Z
RWY 13, Amdt 8D

Manning, SC, KMNI, NDB RWY 2, Amdt 3
Manning, SC, KMNI, VOR/DME OR GPS–A,
Amdt 4B, CANCELED

Moncks Corner, SC, KMKS, RNAV (GPS)
RWY 23, Amdt 1

Winchester, VA, KOKV, RNAV (GPS) RWY
14, Amdt 2

[FR Doc. 2023–13875 Filed 6–29–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9976]

RIN 1545–BO91

Additional Guidance on the Transition From Interbank Offer Rates to Other Reference Rates With Respect to the Interest Rates of a Foreign Bank

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains additional final regulations that provide guidance on the transition away from the use of interbank offer rates (“IBORs”) to other reference rates. Specifically, this regulation provides the replacement rate for the IBOR presently used in the published rate election, which may be used by taxpayers to determine the amount of interest expense attributable to their excess U.S.-connected liabilities and allocable to income that is effectively connected with the conduct of a trade or business within the United States (“ECI”). The final regulations will affect foreign banks that have income that is ECI.

DATES:

Effective date: This regulation is effective on June 30, 2023.

Applicability date: For dates of applicability, see § 1.882–5(f)(3).

FOR FURTHER INFORMATION CONTACT: D. Peter Merkel or Caleb W. Trimm, (202) 317–6938 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations that provide for the replacement of the 30-day IBOR rate presently referenced by § 1.882–5(d)(5)(ii)(B) with the Secured Overnight Financing Rate (“SOFR”) of the same tenor, plus a fixed spread adjustment.

I. Discontinuation of IBORs and Transition to SOFRs

The London Interbank Offered Rate (“LIBOR”) is an interest rate benchmark that was the dominant reference rate used in financial contracts, at one point serving as the benchmark for more than \$200 trillion of contracts worldwide. On July 27, 2017, the Financial Conduct Authority, the United Kingdom regulator tasked with overseeing LIBOR, announced that publication of all currency and term variants of LIBOR, including the U.S. dollar LIBOR (“USD

LIBOR”), may cease after the end of 2021. On March 5, 2021, the administrator of LIBOR, Intercontinental Exchange (ICE) Benchmark Association, announced that publication of the overnight, one-month, three-month, six-month, and 12-month USD LIBORs would cease following the LIBOR publication on June 30, 2023. The ICE Benchmark Association will continue to publish an unrepresentative synthetic USD LIBOR in one-month, three-month, and six-month tenors until September 30, 2024.¹ Publication of all other currency and tenor variants of LIBOR (including the one-week and two-month USD LIBOR) ceased following the LIBOR publication on December 31, 2021.

The Alternative Reference Rate Committee (“ARRC”), whose ex officio members include the Board of Governors of the Federal Reserve System, the Department of the Treasury (“Treasury Department”), the Commodity Futures Trading Commission, and the Office of Financial Research, was convened by the Board of Governors of the Federal Reserve System and the Federal Reserve Bank of New York to identify alternative reference rates that would be both more robust than USD LIBOR and that would comply with standards such as the International Organization of Securities Commissions’ “Principles for Financial Benchmarks.” In 2017, the ARRC identified a SOFR-based rate as its recommended replacement for LIBOR.

In 2021, the ARRC recommended the forward-looking term SOFRs published by the Chicago Mercantile Exchange Group Benchmark Administration, Ltd. in one-month, three-month, and six-month tenors. The ARRC has also recommended static spread adjustments to each of those tenors to adjust for the fact that SOFRs are risk-free rates, while IBORs include an element of bank credit risk. The static spread adjustments are based on the historical median over a 5-year lookback period calculating the difference between USD LIBOR and compounded averages of SOFR, set on

¹ The synthetic USD LIBOR will be the Term SOFR of the same tenor (published by the Chicago Mercantile Exchange Group Benchmark Administration, Ltd.), plus a fixed spread adjustment of 0.11448%, 0.26161%, or 0.42826% for the one-, three-, and six-month tenors, respectively. Financial Conduct Authority, *Article 23D Benchmarks Regulation Draft Notice of Requirements* (April 3, 2023), <https://www.fca.org.uk/publication/libor-notice/article-23d-benchmarks-regulation-usd-draft-notice-requirements.pdf>. This rate is not considered representative because it uses a synthetic methodology to determine rates instead of the panel bank methodology that has historically been used to determine IBORs.

March 5, 2021.² The recommended static spread adjustment for one-month SOFR is 0.11448%.

To support the transition away from USD LIBOR, the ARRC has published recommended fallback language for inclusion in the terms of certain cash products. Contracts governed by U.S. law that reference USD LIBOR but that do not have any (or that have inadequate) fallback provisions are generally required by the Adjustable Interest Rate Act (“LIBOR Act”), Public Law 117–103, div. U, to use the SOFR of the same tenor, plus a static spread adjustment. The static spread adjustments to SOFR for each USD tenor required by the LIBOR Act are the same as those recommended by the ARRC.

II. Regulatory Background

The transition from IBORs to SOFRs or other reference rates may give rise to various tax issues. To minimize market disruption and facilitate an orderly transition in connection with the discontinuation of LIBOR and other IBORs, the Treasury Department and IRS published proposed regulations (REG–118784–18) in the **Federal Register** (84 FR 54068) on October 9, 2019 (“2019 Proposed Regulations”).

One issue addressed by the 2019 Proposed Regulations was the election provided by § 1.882–5(d)(5)(ii)(B). A foreign corporation that has a U.S. branch or other trade or business within the United States applies § 1.882–5 to determine its interest expense allocable under section 882(c) to its ECI. If a foreign corporation uses the method described in § 1.882–5(b) through (d), that foreign corporation could have liabilities attributable to its U.S. branch (U.S.-connected liabilities) that exceed its U.S.-booked liabilities (excess U.S.-connected liabilities). When a foreign corporation has excess U.S.-connected liabilities, § 1.882–5(d)(5)(ii)(A) entitles the foreign corporation to increase its interest expense allocable to its ECI in an amount determined by reference to the average U.S.-dollar borrowing cost on all U.S.-dollar liabilities other than its U.S.-booked liabilities. If the foreign corporation is a bank, it may elect under § 1.882–5(d)(5)(ii)(B) to use a published average 30-day LIBOR for the year rather than the actual rate computed under § 1.882–5(d)(5)(ii)(A). Because use of that election will no longer be possible when LIBOR is phased out, the 2019 Proposed Regulations included a

proposal to replace 30-day USD LIBOR referenced in § 1.882–5(d)(5)(ii)(B) with a yearly average SOFR. Because SOFR is an overnight risk-free rate, the Treasury Department and the IRS acknowledged that the yearly average SOFR was likely to result in a lower rate than the 30-day LIBOR calculation previously allowed under § 1.882–5(d)(5)(ii)(B) and requested comments on whether another rate might be more appropriate.

Following publication of the 2019 Proposed Regulations, the Treasury Department and the IRS received one comment regarding the proposal to use yearly average SOFR in place of 30-day USD LIBOR for the election available under § 1.882–5(d)(5)(ii)(B). The comment noted two key differences between 30-day LIBOR and the yearly average SOFR, which the commenter stated made the yearly average SOFR an inappropriate substitute for 30-day LIBOR. First, SOFR is a risk-free rate, while LIBOR is an unsecured rate. Second, SOFR is an overnight rate, while the 30-day LIBOR is a one-month rate. The comment noted that SOFR removes the credit risk premium and term liquidity premium from the cost of borrowing as compared to 30-day LIBOR. The comment, however, did not identify a more reasonable substitute for 30-day LIBOR at that time and recommended that the Treasury Department and the IRS defer finalizing the proposed rule under § 1.882–5(d)(5)(ii)(B) because a yearly average SOFR calculation was not a reasonable replacement rate for 30-day USD LIBOR.

On January 4, 2022, the Treasury Department and the IRS published final regulations (TD 9961) in the **Federal Register** (87 FR 166) relating to the transition from IBORs to other reference rates (“2022 Final Regulations”). The 2022 Final Regulations did not finalize the proposed change to § 1.882–5(d)(5)(ii)(B). Instead, the Treasury Department and the IRS sought additional comments regarding the appropriate replacement rate for 30-day USD LIBOR for the purpose of the election under § 1.882–5(d)(5)(ii)(B).

Following the publication of the 2022 Final Regulations, the Treasury Department and the IRS received one additional comment regarding the appropriate replacement rate for the 30-day USD LIBOR rate referenced by § 1.882–5(d)(5)(ii)(B).

This comment is available for public inspection at <https://www.regulations.gov> or upon request. No public hearing was requested, and none was held. After consideration of the comments, the Treasury Department and the IRS adopt the 2019 Proposed

Regulation as amended by this Treasury decision (“final regulations”).

Summary of Comments and Explanation of Revisions

I. Appropriate Replacement Rate for 30-Day LIBOR

In response to the request for additional comments in TD 9961, one comment was received relating to the 30-day USD LIBOR replacement in § 1.882–5(d)(5)(ii)(B). The comment made three recommendations for the final regulations under § 1.882–5(d)(5)(ii)(B).

A. One-Month Term SOFR Plus a Static Spread Adjustment

First, the comment recommended finalizing the regulation using the one-month term SOFR plus static spread adjustment of 0.11448% as recommended by the ARRC (which endorsed Term SOFR rates in June of 2021 and spread adjustments in October of 2021) and codified in the LIBOR Act (enacted in December of 2021). The comment noted that the one-month term SOFR plus a fixed spread adjustment accounts for some of the differences between SOFR and LIBOR rates and implied that one-month term SOFR plus static spread adjustment of 0.11448% is a more appropriate replacement than yearly average SOFR. The published rate election provides eligible taxpayers with administrative relief from the burden of calculating their actual borrowing rate, which is based on data maintained outside the United States.

The final regulations adopt this recommendation. The ARRC, whose ex officio members include the Treasury Department, has generally recommended that contracts referencing USD LIBOR adopt fallback provisions that reference the term SOFR of the same tenor, plus a static spread adjustment. The Treasury Department has supported the recommendations of the ARRC in prior guidance issued in Revenue Procedure 2020–44, 2020–45 I.R.B. 991 and the 2022 Final Regulations. In addition, contracts governed by U.S. law that have not voluntarily adopted such fallback provisions are generally required by the LIBOR Act to use the SOFR of the same tenor, plus the ARRC-recommended static spread adjustment, as a matter of law. Public Law 117–103, div. U. Accordingly, both the Treasury Department and the U.S. Congress have endorsed, or required, the use of a term SOFR of the same tenor, plus the ARRC-recommended static spread adjustment, as a replacement for term USD LIBORs. Because the published rate election

² For an explanation of the SOFR averaging calculation, see Federal Reserve Bank of New York, *Additional Information About the Reference Rates Administered by the New York Fed*, <https://www.newyorkfed.org/markets/reference-rates/additional-information-about-reference-rates>.

available under § 1.882–5(d)(5)(ii)(B) references 30-day LIBOR, the one-month term SOFR (plus static spread adjustment) is the most appropriate replacement rate.

B. Alternative Method Approximating Actual Rate

The comment also recommended that the final regulations allow taxpayers to use a rate that reasonably approximates the bank's actual rate and that is consistently applied from year to year. This recommendation is based on the approach taken in regulations that were in effect from 1981 through 1996. TD 7749, 46 FR 1681 (Jan. 7, 1981) (codified at former § 1.882–5(b)(3)(i)(B)). This historical regulation provided that, if information needed to calculate the taxpayer's actual interest rate could not be reasonably obtained, then the taxpayer could determine its interest rate by applying any method that reasonably approximated its actual interest rate and that was consistently applied year over year, including, for example, approximating its interest rate by reference to 30-day LIBOR. *Id.* at 1684–85. The comment expressed concern that the one-month term SOFR plus static spread adjustment may be less than the actual cost of borrowing; however, for some taxpayers it may not be worthwhile or possible for the corporation to calculate its actual borrowing rate.

The final regulations do not adopt this recommendation. An approach based on a reasonable approximation of a taxpayer's actual interest would establish a different method for determining a taxpayer's borrowing rate that does not provide the certainty, accuracy, and simplicity of a published rate election. Additionally, the IRS would face significant challenges in administering such a rule. For example, the comment did not suggest any standard by which the IRS might determine whether a taxpayer's method is a reasonable approximation of its actual borrowing rate.

Finally, data from recent filing years indicates that the actual rate calculation is not a significant burden to taxpayers. For taxable years 2020 and 2021 (the most recent years for which data is available), a majority of foreign banks with excess U.S.-connected liabilities chose to calculate their actual rate rather than use the published rate election. In both years, approximately 80% of such taxpayers opted to calculate their actual rate, while less than 20% chose to use the published rate election available under § 1.882–5(d)(5)(ii)(B).

C. Mechanism for Endorsing Additional Replacement Rates

Finally, the comment recommended that the final regulations include a mechanism for identifying additional qualified alternative reference rates via Internal Revenue Bulletin, Revenue Procedure, or another similar notice. The final regulations do not adopt this recommendation. The Treasury Department and the IRS do not anticipate a need to name additional alternative reference rates, and, if the need does arise in the future, the Treasury Department and the IRS may prefer to propose any new alternative reference rate through the regulatory process.

II. Application of the Published Rate Election by the IRS in an Examination

If a taxpayer failed to file a timely return or incorrectly determined that it did not have excess U.S.-connected liabilities, § 1.882–5(d)(5)(ii)(B) allowed the Director of Field Operations to calculate the taxpayer's interest expense with respect to excess U.S.-connected liabilities using either the taxpayer's actual rate or the published rate provided by § 1.882–5(d)(5)(ii)(B). The final regulations amend this rule to require the Director of Field Operations to use the published rate in order to reduce the administrative burden of calculating the actual rate for both the IRS and taxpayers.

III. Transitional Rule for Taxable Years Including the Date of LIBOR Cessation

For a taxable year that begins before and ends after the USD LIBOR cessation date of June 30, 2023, a taxpayer that makes the published rate election available under § 1.882–5(d)(5)(ii)(B) must calculate a blended published rate average for the taxable year which uses the 30-day USD LIBOR for the portion of its taxable year ending on June 30, 2023, and the one-month Term SOFR, plus static spread adjustment, for the portion of its taxable year beginning on July 1, 2023.

IV. Applicability Date

These final regulations apply to taxable years ending after June 30, 2023.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended.

Therefore, a regulatory impact assessment is not required.

II. Regulatory Flexibility Act

The final regulations affect any foreign bank that has ECI and that has excess U.S.-connected liabilities, but which cannot reasonably calculate its actual borrowing rate. The number of small entities potentially affected by the final regulations is unknown; however, it is unlikely to be a substantial number because the final regulations only affect foreign banks that operate in the United States. In addition, data collected from Forms 1120–F, Schedule I filed in recent taxable years indicates that fewer than 100 total taxpayers are foreign banks with both ECI and excess U.S.-connected liabilities. The data from Forms 1120–F, Schedule I shows that the number of foreign banks that elected to use the 30-day USD LIBOR rate to compute the interest expense attributable to their excess U.S.-connected liabilities varied from year to year. In some years, as many as 50 foreign banks made the election on Schedule I to use the 30-day USD LIBOR rate; in other years, fewer than ten taxpayers made that election. The Secretary has determined that the economic impact on any small entities affected by the final regulations is not significant.

The final regulations provide that the annual published rate election available under § 1.882–5(d)(5)(ii)(B) will be modified by substituting the one-month term SOFR, plus a static spread adjustment, for 30-day USD LIBOR. The rule does not require taxpayers to collect additional information to determine whether the taxpayer is eligible for the election. Additionally, the rule does not impose any new costs on taxpayers because it only replaces the published rate used for the purpose of the election and does not affect a taxpayer's obligation with respect to the information to be gathered and reported.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Secretary hereby certifies that these final regulations will not have a significant economic impact on a substantial number of small entities.

III. Section 7805(f)

Pursuant to section 7805(f), the proposed regulations (REG–118784–18) preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact on small business, and no comments were received.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

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

Statement of Availability of IRS Documents

IRS Notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at <https://www.irs.gov>.

Drafting Information

The principal authors of these regulations are D. Peter Merkel and Caleb W. Trimm of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, the Treasury Department and IRS amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by revising the entry for § 1.882–5 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.882–5 also issued under 26 U.S.C. 882(c), 26 U.S.C. 864(e), 26 U.S.C. 988(d), and 26 U.S.C. 7701(l).

■ **Par. 2.** Section 1.882–5 is amended by revising the fourth sentence of paragraph (a)(7)(i) and paragraphs (d)(5)(ii)(B) and (f) to read as follows:

§ 1.882–5 Determination of interest deduction.

(a) * * *

(7) * * *

(i) * * * An elected method (other than the fair market value method under paragraph (b)(2)(ii) of this section, or the published rate election in paragraph (d)(5)(ii) of this section) must be used for a minimum period of five years before the taxpayer may elect a different method. * * *

* * * * *

(d) * * *

(5) * * *

(ii) * * *

(B) *Annual published rate election—*
(1) *In general.* For each taxable year in which a taxpayer is a bank within the meaning of section 585(a)(2)(B) (without regard to the second sentence of section 585(a)(2)(B) or whether any such activities are effectively connected with a trade or business within the United States), the taxpayer may elect to compute the interest expense attributable to excess U.S.-connected liabilities by using the average published one-month Term Secured Overnight Financing Rate published by the Chicago Mercantile Exchange Group Benchmark Administration, Ltd. (or any successor administrator) (“Term SOFR”) for the taxable year, plus a static spread adjustment of 0.11448%, rather than the interest rate provided in paragraph (d)(5)(ii)(A) of this section. A taxpayer may elect to apply the rate provided in this paragraph (d)(5)(ii)(B) on an annual basis and does not require the consent of the Commissioner to change this election in a subsequent taxable year. If a taxpayer that is eligible to make the published rate election either does not file a timely return or files a calculation with no excess U.S.-connected liabilities and it is later determined by the Director of Field Operations that the taxpayer has excess U.S.-connected liabilities, then the Director of Field Operations will apply the interest rate

provided under this paragraph (d)(5)(ii)(B) to the taxpayer’s excess U.S.-connected liabilities in determining interest expense.

(2) *Transitional rule for taxable years including June 30, 2023.* For a taxable year that includes June 30, 2023, a taxpayer that makes the annual published rate election must compute the interest expense attributable to excess U.S.-connected liabilities by ratably using the average 30-day U.S. dollar London Interbank Offered Rate for the portion of its taxable year ending on June 30, 2023, and the average one-month Term SOFR, plus a static spread adjustment of 0.11448%, for the portion of its taxable year beginning on July 1, 2023.

* * * * *

(f) *Applicability date—*(1) *General rule.* Except as provided in paragraph (f)(3) of this section, this section is applicable for tax years ending on or after August 15, 2009. A taxpayer, however, may choose to apply § 1.882–5T, rather than applying the regulations in this section, for any taxable year beginning on or after August 16, 2008, but before August 15, 2009.

(2) [Reserved]

(3) *Applicability date for published rate election.* Paragraphs (a)(7)(i) and (d)(5)(ii)(B) of this section apply to taxable years ending after June 30, 2023. For taxable years ending before July 1, 2023, see § 1.882–5(d)(5)(ii)(B) (as contained in 26 CFR part 1, revised as of April 1, 2023).

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

Approved: June 19, 2023.

Lily Batchelder,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2023–13890 Filed 6–29–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DOD–2023–OS–0044]

RIN 0790–AL54

Privacy Act of 1974; Implementation

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

ACTION: Direct final rule.

SUMMARY: The DoD is amending its regulations to remove the exemption rules associated with 14 systems of

records notices (SORNs) established for the DoD Components listed in the **SUPPLEMENTARY INFORMATION** section, under the Privacy Act of 1974, as amended.

Elsewhere in this issue of the **Federal Register**, the DoD is giving concurrent notice of the rescindment of 26 SORNs, including those that correspond to the exemption rules being removed by this rule amendment. This rule is being published as a direct final rule as the Department does not expect to receive any adverse comments. If such comments are received, this direct final rule will be withdrawn and a proposed rule for comments will be published.

DATES: The rule is effective on September 8, 2023, unless comments are received that would result in a contrary determination. Comments will be accepted on or before August 29, 2023.

ADDRESSES: You may submit comments, identified by docket number, Regulation Identifier Number (RIN), and title, by any of the following methods.

* *Federal Rulemaking Portal:* <https://www.regulations.gov>.

Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <https://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

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

SUPPLEMENTARY INFORMATION:

I. Privacy Act Exemption

The DoD is amending 32 CFR part 310 to remove the exemption rules associated with the following 14 systems of records notices (SORNs) established for the DoD Components.

Department of the Air Force SORNs

System identifier and name. F051 AFJA I, Military Justice and Magistrate Court Records

System identifier and name. F033 AF A, Information Requests—Freedom of Information Act

System identifier and name. F033 AF B, Privacy Act Request File

Department of the Army SORN

System identifier and name. A0340-21 OAA, Privacy Case Files

Department of the Navy SORNs

System identifier and name. NM05211-1, Privacy Act Request/Amendment Files and Tracking System

System identifier and name. NM05720-1, FOIA Request/Appeal Files and Tracking System

Defense Intelligence Agency SORN

System identifier and name. LDIA 0010, Information Requests-Freedom of Information Act (FOIA) and Privacy Act

Defense Logistics Agency SORN

System identifier and name. S510.30, Freedom of Information Act/Privacy Act Requests and Administrative Appeal Records

Defense Security Service SORN

System identifier and name. V1-01, Privacy and Freedom of Information Request Records

Defense Threat Reduction Agency SORN

System identifier and name. HDTRA 021, Freedom of Information Act and Privacy Act Case Files

National Guard Bureau SORN

System identifier and name. INGB 001, Freedom of Information Act (FOIA) and Privacy Act (PA) Case Files

Office of the Inspector General SORN

System identifier and name. CIG-01, Privacy Act and Freedom of Information Act Case Files

Office of the Secretary of Defense SORNs

System identifier and name. DWHS E02, Freedom of Information Act (FOIA) Case Files

System identifier and name. DWHS E04, Privacy Act Case Files

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

When a system of records is no longer required to be collected or maintained, the system of records may be

discontinued. The notice for that system of record is rescinded in the **Federal Register**, and the records covered by the rescinded system of records are lawfully transferred or disposed of in accordance with applicable requirements. At the time of rescindment or following rescindment for the system of records notice, Federal agencies will seek to also rescind the associated exemption rules within the Code of Federal Regulations.

II. Direct Final Rulemaking

This rule is being published as a direct final rule as the Department does not expect to receive any significant adverse comments. If such comments are received, this direct final rule will be cancelled and a proposed rule for comments will be published. If no such comments are received, this direct final rule will become effective 10 days after the comment period expires.

For purposes of this rulemaking, a significant adverse comment is one that explains (1) why the rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the rule will be ineffective or unacceptable without a change. In determining whether a significant adverse comment necessitates withdrawal of this direct final rule, the Department will consider whether the comment raises an issue serious enough to warrant a substantive response had it been submitted in a standard notice-and-comment process. 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.

The DoD is modifying 32 CFR part 310 by rescinding the following regulation provisions (in their entirety) due to the underlying SORNs being rescinded (most of them concurrently by associated public notice):

- 32 CFR 310.14(e)(7), System identifier and name. F051 AF JA F, Courts—Martial and Article 15 Records.
- 32 CFR 310.14(f)(20), System identifier and name. F033 AF A, Information Requests—Freedom of Information Act.
- 32 CFR 310.14(f)(21), System identifier and name. F033 AF B, Privacy Act Request Files.
- 32 CFR 310.15(g)(21), System identifier and name. A0340-21 OAA, Privacy Case Files.
- 32 CFR 310.16(a)(22), System identifier and name. NM05211-1, Privacy Act Request Files and Tracking System.
- 32 CFR 310.16(a)(23), System identifier and name. NM05720-1, FOIA

Request/Appeal Files and Tracking System.

- 32 CFR 310.20(b)(8), System identifier and name. LDIA 0010, Information Requests—Freedom of Information Act (FOIA) and Privacy Act.

- 32 CFR 310.21(c)(6), System identifier and name. S510.30, Freedom of Information Act/Privacy Act Requests and Administrative Appeal Records.

- 32 CFR 310.22(b)(1), System identifier and name. V1–01, Privacy and Freedom of Information Request Records.

- 32 CFR 310.23(a)(3), System identifier and name. HDTRA 021, Freedom of Information Act and Privacy Act Request Case Files.

- 32 CFR 310.25(e)(1), System identifier and name. INGB 001, Freedom of Information Act (5 U.S.C.) and Privacy Act (5 U.S.C. 552a) Case Files.

- 32 CFR 310.28(c)(5), System identifier and name. CIG 01, Privacy Act and Freedom of Information Act Case Files.

- 32 CFR 310.29(c)(12), System identifier and name. DFOISR 05, Freedom of Information Act Case Files.

- 32 CFR 310.29(c)(13), System identifier and name. DFOISR 10, Privacy Act Case Files.

Regulatory Analysis

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

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

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. DoD will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and

the Comptroller General of the United States. A major rule may take effect no earlier than 60 calendar days after Congress receives the rule report or the rule is published in the **Federal Register**, whichever is later. This rule is not a “major rule” as defined by 5 U.S.C. 804(2).

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

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

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

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

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

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

Executive Order 13132, “Federalism”

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct

requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This rule will not have a substantial effect on State and local governments.

Executive Order 13175, “Consultation and Coordination With Indian Tribal Governments”

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

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is amended as follows:

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

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

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

§ 310.14 [Amended]

■ 2. Amend § 310.14 by removing and reserving paragraphs (e)(7) and (f)(20) and (21).

§ 310.15 [Amended]

■ 3. Amend § 310.15 by removing and reserving paragraph (g)(21).

§ 310.16 [Amended]

■ 4. Amend § 310.16 by removing and reserving paragraphs (a)(22) and (23).

§ 310.20 [Amended]

■ 5. Amend § 310.20 by removing and reserving paragraph (b)(8).

§ 310.21 [Amended]

■ 6. Amend § 310.21 by removing and reserving paragraph (c)(6).

§ 310.22 [Amended]

■ 7. Amend § 310.22 by removing and reserving paragraph (b)(1).

§ 310.23 [Amended]

■ 8. Amend § 310.23 by removing paragraph (a)(3).

§ 310.25 [Amended]

■ 9. Amend § 310.25 by removing and reserving paragraph (e)(1).

§ 310.28 [Amended]

■ 10. Amend § 310.28 by removing and reserving paragraph (c)(5).

§ 310.29 [Amended]

■ 11. Amend § 310.29 by removing and reserving paragraphs (c)(12) and (13).

Dated: June 27, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2023–13969 Filed 6–29–23; 8:45 am]

BILLING CODE 5001–06–P

**DEPARTMENT OF HOMELAND
SECURITY****Coast Guard****33 CFR Part 147**

[Docket Number USCG–2023–0277]

RIN 1625–AA00

**Safety Zone; Vineyard Wind 1 Wind
Farm Project Area, Outer Continental
Shelf, Lease OCS–A 0501, Offshore
Massachusetts, Atlantic Ocean**

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

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing 63 temporary 500-meter safety zones around the construction of 62 wind turbine generators (WTGs) and one electrical service platform (ESP) located in the Vineyard Wind 1 Wind Farm (VW1WF) project area within federal waters on the Outer Continental Shelf (OCS), specifically in the northern portion of Bureau of Ocean Energy Management (BOEM) Renewable Energy Lease Area OCS–A 0501, approximately 12 nautical miles (NM) offshore of Martha's Vineyard, Massachusetts and 12 NM offshore Nantucket, Massachusetts. This action is necessary to provide for the safety of life, property, and the environment during the planned construction of each facility's monopile type foundation and subsequent installation of the WTGs turbines and ESP platform from June 27, 2023, to May 31, 2024. When enforced, only attending vessels and those vessels specifically authorized by the First Coast Guard District Commander, or a designated representative, are permitted to enter or remain in the temporary safety zones.

DATES: This rule is effective without actual notice from June 30, 2023, through 11:59 p.m. on May 31, 2024. For the purposes of enforcement, actual notice will be used from June 27, 2023, until June 30, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2023–0277 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Craig Lapiejko, Waterways Management, at Coast Guard First District, telephone 617–603–8592, email craig.d.lapiejko@uscg.mil.

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

BOEM Bureau of Ocean Energy
Management
BNM Broadcast Notice to Mariners
CFR Code of Federal Regulations
DD Degrees Decimal
DHS Department of Homeland Security
EIS Environmental Impact Statement
FR Federal Register
MSIB Marine Safety Information Bulletin
NPRM Notice of proposed rulemaking
OCS Outer Continental Shelf
OSS Offshore Substation
LNM Local Notice to Mariners
NAD 83 North American Datum of 1983
NM Nautical Mile
§ Section
SMIB Safety Marine Information Broadcast
U.S.C. United States Code
WTG Wind Turbine Generator
VHF–FM Very High Frequency—Frequency
Modulation
VW1WF Vineyard Wind 1 Wind Farm

**II. Background, Purpose, and Legal
Basis**

On March 15, 2023, Vineyard Wind, LLC, an offshore wind farm developer, notified the Coast Guard that they plan to begin construction of facilities in the VW1WF project area within federal waters on the OCS, specifically in the northern portion of BOEM Renewable Energy Lease Area OCS–A 0501, approximately 12 NM offshore Martha's Vineyard, Massachusetts and 12 NM offshore Nantucket, Massachusetts in June 2023.

After determining that establishment of safety zones was necessary to provide for the safety of life, property, and the environment during the anticipated construction of the structures, on May 3, 2023, the Coast Guard published a notice of proposed rulemaking (NPRM) titled “Safety Zone; Vineyard Wind 1 Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0501, Offshore Massachusetts, Atlantic Ocean” (88 FR 27839). There we explained the basis for the NPRM and invited comments on our proposed regulatory action related to the

establishment of safety zones around the construction of 62 WTGs and one ESP located in the VW1WF project area. Five comments were received during the comment period that ended June 2, 2023.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The comment period for the NPRM associated with the VW1WF project area ended on June 2, 2023, and construction for the project has already begun. Thus, there is insufficient time to allow for 30-days before the rule becomes effective. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety risks associated with the extremely complex and unusually hazardous construction of these OCS facilities including hydraulic pile driving hammer operations, heavy lift operations, overhead cutting operations, potential falling debris, increased vessel traffic, and stationary barges in close proximity to the facilities and each other.

Based on these circumstances, the First Coast Guard District Commander has determined that establishment of 63 safety zones through rulemaking is warranted to ensure the safety of life, property, and the environment within a 500-meter radius of each of the 63 facilities during their construction.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority provided in 14 U.S.C. 544, 43 U.S.C. 1333, and Department of Homeland Security (DHS) Delegation No. 00170.1, Revision No. 01.3. As an implementing regulation of this authority, 33 CFR part 147 permits the establishment of safety zones for non-mineral energy resource permanent or temporary structures located on the OCS for the purpose of protecting life and property on the facilities, appurtenances and attending vessels, and on the adjacent waters within the safety zone (see 33 CFR 147.10). Accordingly, a safety zone established under 33 CFR part 147 may also include provisions to restrict, prevent, or control certain activities, including access by vessels or persons to maintain safety of life, property, and the environment.

**IV. Discussion of Comments, Changes,
and the Rule**

As noted above, the Coast Guard received five public comments on the NPRM published May 3, 2023. All five commenters expressed general opposition to wind farm construction.

Three commenters expressed specific opposition to the proposed rule and the enforcement of safety zones around construction. Two commenters questioned Coast Guard's authority to establish safety zones on the Outer Continental Shelf and stated concerns that impact of safety zones was not analyzed by BOEM during the VW1WF Final Environmental Impact Statement (EIS) process. We provide a detailed discussion of those comments below.

First, the Coast Guard is issuing this rule under the authority provided in 14 U.S.C. 544, 43 U.S.C. 1333, and Department of Homeland Security (DHS) Delegation No. 00170.1, Revision No. 01.3. On January 1, 2021, Congress enacted the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (NDAA), Public Law 116–283, 134 Stat. 3388. Section 9503 of the NDAA amended Section 4(a)(1) of the Outer Continental Shelf Lands Act (43 U.S.C. 1333(a)(1)) to specifically include non-mineral energy resources. On January 11, 2023, the Coast Guard published a final rule titled “Safety Zones; Technical and Conforming Amendments” (88 FR 1511), which made non-substantive technical and conforming amendments to the Code of Federal Regulations (CFR) at part 147. That rule enabled the Coast Guard to place safety zones for non-mineral energy resource facilities on the Outer Continental Shelf in part 147 where other OCS safety zone regulations are located.

As an implementing regulation of this authority, 33 CFR part 147 permits the establishment of safety zones for non-mineral energy resource permanent or temporary structures located on the OCS for the purpose of protecting life and property on the facilities, appurtenances and attending vessels, and on the adjacent waters within the safety zone (see 33 CFR 147.10). Accordingly, a safety zone established under 33 CFR part 147 may also include provisions to restrict, prevent, or control certain activities, including access by vessels or persons to maintain safety of life, property, and the environment.

Second, while the safety zones were not analyzed by BOEM during the EIS process, the Coast Guard has analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard's compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f). The Coast Guard has determined that the action is one of

a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule establishes a safety zone around an OCS facility to protect life, property, and the marine environment and categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the subject docket. For instructions on locating the docket, see the **ADDRESSES** section of the preamble.

One commenter disagreed with the finding of no significant economic impact on small entities. While this rule may affect some owners or operators of small entities, the Coast Guard believes these safety zones will have a minimal economic impact because the safety zones are temporarily enforced, allow for deviation requests, and do not significantly impact transits. Vessels will only be prohibited from the regulated zone during periods of actual construction activity. The Coast Guard anticipates the enforcement period at each location to last approximately 48 hours. Vessel traffic will be able to pass safely around each safety zone using an alternate route. Use of an alternate route will likely cause minimal delay for vessels in reaching their destination depending on other traffic in the area and vessel speeds. Vessels will be permitted to request deviations from this rule to transit through a safety zone. Such requests would be considered on a case by case basis and may be authorized by the First Coast Guard District Commander.

That same commenter expressed concerns about the effective date of the safety zones not aligning with the dates and timing of actual construction and that there is nothing preventing the Coast Guard from enacting future exclusion zones.

Although the Coast Guard has been aware of the VW1WF project area for several years, the Coast Guard was only recently granted the authority to establish safety zones for non-mineral energy resource facilities on the Outer Continental Shelf. The Coast Guard was notified of the estimated construction details on March 15, 2023, and was notified of the exact construction commencement date after the NPRM was published. The Coast Guard views public participation as essential to effective rulemaking and determined that it was in the public interest to open the comment period. The 63 safety zones established by this rule are intended to be temporary and are

enforceable only through May 31, 2024. If the project is completed before May 31, 2024, enforcement of the safety zones will be suspended, and notice will be provided via Local Notice to Mariners. The implementation of additional safety zones would require additional notice and comment rulemaking.

One commenter offered two recommendations for the Coast Guard to consider when establishing temporary safety zones.

First, the commenter recommended additional means of making notice of each enforcement period. Recommendations included: directly notifying local commercial fishing organizations, creating a dedicated web page, and requiring vessel on-scene during all construction activities whose sole role is to patrol the area and ensure vessels are aware of the safety zone. As stated in the proposed rule, the Coast Guard will make notice of each enforcement period via the First Coast Guard District Local Notice to Mariners (LNM). The LNM has historically been the primary means for disseminating information concerning aids to navigation, hazards to navigation, and other marine information of interest to mariners on the waters of the United States. The First Coast Guard District LNM is available online and can be found at its dedicated website at <https://www.navcen.uscg.gov>. Notices are published weekly. Interested parties may subscribe to receive email updates at https://service.govdelivery.com/accounts/USDHSCG/subscribe/new?topic_id=USDHSCG_65. The Coast Guard believes the use of the LNM to be the most efficient means to distribute information concerning enforcement periods for these safety zones.

The proposed rule stated that the Coast Guard would issue a Broadcast Notice to Mariners (BNM) via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency or hazardous condition. The Coast Guard now offers an online subscription service in addition to the standard VHF BNM broadcasts which, traditionally, was the only method to receive this vital navigational information. Mariners may now use a subscription service to plan for underway periods and can receive updates to navigational hazards in near-real-time without waiting on scheduled VHF broadcasts. Sign up to receive BNMs via email for your waterway at <https://www.navcen.uscg.gov/subscribe-email-rss-feeds>.

The Coast Guard will also issue Safety Marine Information Broadcasts (SMIB) via marine channel 16 (VHF–FM) for each Safety Zone starting an hour before

and broadcasting four times per day for the duration of the safety zone and Marine Safety Information Bulletins (MSIB) are distributed via email. MSIBs will also be posted on Coast Guard Sector Southeastern New England's Homeport at [https://homeport.uscg.mil/port-directory/southeastern-new-england-\(providence\)](https://homeport.uscg.mil/port-directory/southeastern-new-england-(providence)).

Additionally, Vineyard Wind will provide dedicated safety and scout vessels on scene to provide advisory information.

Second, the commenter recommended the definition of a designated representative be expanded if requests to deviate from the rule to transit through a safety zone becomes time consuming. Specifically, the recommendation was to expand the definition of "designated representative" to account for need to process rule deviations in a timely manner. The Coast Guard does not anticipate delays from our designated representatives. Upon further examination, the Coast Guard believes that the current definition of "designated representative" should be maintained. Based on the particular details of this offshore construction project, including the short duration of the enforcement period (approximately 48 hours during active construction), the more distant offshore location which sees less vessel traffic, and the types of large vessels that are most likely to navigate in the vicinity of the safety zones (commercial shipping, fishing, and tugs with tows), the Coast Guard finds no compelling necessity to broaden representative designation or the authority to permit passage through

and around the safety zones. Maintaining designation to Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the First Coast Guard District Commander in the enforcement of the safety zones will ensure consistent application.

The First Coast Guard District has factored applicable statutes and regulations into the subject rule. Applicable authorities are cited in section III. of this document.

After considering the comments discussed above, the Coast Guard determined that no additional changes should be made to the regulatory text. The rule ensures consistency, sufficient notice, and improved safety while minimizing impact on vessel transit.

There is one change to the regulatory text of this rule from the proposed rule in the NPRM to account for the delay in the effective date.

This rule establishes 63 temporary 500-meter safety zones around the construction of 62 WTGs and one ESP on the OCS from June 27, 2023, through 11:59 p.m. on May 31, 2024.

The construction of these facilities is expected to take place in mixed phases alternating between the installation of several monopile type foundations followed by the installation of the upper structures then repeating this process throughout the project area until all 63 facilities have been completed. The 63 temporary safety zones would be enforced individually as construction progresses from one structure location to the next throughout the entire process for a period lasting approximately 48

hours. The Coast Guard will make notice of each enforcement period via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF-FM) as soon as practicable in response to an emergency or hazardous condition. The Coast Guard is publishing this rulemaking to be effective, and enforceable, through May 31, 2024, to encompass any construction delays due to weather or other unforeseen circumstances. If the project is completed before May 31, 2024, enforcement of the safety zones would be suspended, and notice given via Local Notice to Mariners.

Additional information about the construction process of the VW1WF can be found at <https://www.boem.gov/vineyard-wind>.

The 63 temporary 500-meter safety zones around the construction of 62 WTGs and one ESP are in the VW1WF project area, specifically in the northern portion of BOEM Renewable Energy Lease Area OCS-A 0501, approximately 12 NM offshore of Martha's Vineyard, Massachusetts and 12 NM offshore Nantucket, Massachusetts, within federal waters on the OCS.

The positions of each individual safety zone will be referred to using a unique alpha-numeric naming convention outlined in the "Rhode Island and Massachusetts Structure Labeling Plot (West)." ¹

Aligning with authorities under 33 CFR 147.15, the safety zones will include the area within 500-meters of the center point of the positions provided in the table below expressed in Decimal Degrees (DD) based on North American Datum 1983 (NAD 83).

Name	Facility type	Latitude	Longitude
AL38	WTG	N 41.1370161	W - 70.4638911
AM37	ESP	N 41.1200616	W - 70.4851682
AM38	WTG	N 41.1203387	W - 70.4635204
AM39	WTG	N 41.1206168	W - 70.4414663
AN36	WTG	N 41.1030927	W - 70.5072461
AN37	WTG	N 41.1033791	W - 70.4851982
AN38	WTG	N 41.1036612	W - 70.4631500
AN39	WTG	N 41.1039392	W - 70.4411014
AP35	WTG	N 41.0861251	W - 70.5289069
AP36	WTG	N 41.0864155	W - 70.5068649
AP37	WTG	N 41.0867017	W - 70.4848226
AP38	WTG	N 41.0869837	W - 70.4627799
AP39	WTG	N 41.0872615	W - 70.4407369
AP40	WTG	N 41.0875351	W - 70.4186937
AP41	WTG	N 41.0878044	W - 70.3966501
AQ34	WTG	N 41.0691535	W - 70.5505566
AQ35	WTG	N 41.0694480	W - 70.5285205
AQ36	WTG	N 41.0697382	W - 70.5064840
AQ37	WTG	N 41.0700243	W - 70.4844472
AQ38	WTG	N 41.0703061	W - 70.4624101
AQ39	WTG	N 41.0705837	W - 70.4403727

¹ The Rhode Island and Massachusetts Structure Labeling Plot (West) is an attachment to the Conditions of Construction and Operations Plan

Approval Lease Number OCS-A 0517 (boem.gov) and can be found at [https://www.boem.gov/sites/](https://www.boem.gov/sites/default/files/documents/renewable-energy/state-activities/SFWF-COP-Terms-and-Conditions.pdf)

[default/files/documents/renewable-energy/state-activities/SFWF-COP-Terms-and-Conditions.pdf](https://www.boem.gov/sites/default/files/documents/renewable-energy/state-activities/SFWF-COP-Terms-and-Conditions.pdf)

Name	Facility type	Latitude	Longitude
AQ40	WTG	N 41.0708571	W - 70.4183350
AQ41	WTG	N 41.0711263	W - 70.3962970
AQ42	WTG	N 41.0713913	W - 70.3742587
AR33	WTG	N 41.0521781	W - 70.5721951
AR34	WTG	N 41.0524766	W - 70.5501649
AR35	WTG	N 41.0527709	W - 70.5281343
AR36	WTG	N 41.0530609	W - 70.5061034
AR37	WTG	N 41.0533468	W - 70.4840722
AR38	WTG	N 41.0536285	W - 70.4620407
AR39	WTG	N 41.0539059	W - 70.4400088
AR40	WTG	N 41.0541792	W - 70.4179767
AR41	WTG	N 41.0544482	W - 70.3959442
AR42	WTG	N 41.0547130	W - 70.3739115
AS32	WTG	N 41.0351987	W - 70.5938225
AS33	WTG	N 41.0355012	W - 70.5717982
AS34	WTG	N 41.0357995	W - 70.5497735
AS35	WTG	N 41.0360937	W - 70.5277485
AS36	WTG	N 41.0363836	W - 70.5057231
AS37	WTG	N 41.0366693	W - 70.4836975
AS38	WTG	N 41.0369508	W - 70.4616715
AS39	WTG	N 41.0372281	W - 70.4396452
AS40	WTG	N 41.0375012	W - 70.4176186
AS41	WTG	N 41.0377701	W - 70.3955918
AS42	WTG	N 41.0380347	W - 70.3735646
AT33	WTG	N 41.0188243	W - 70.5714016
AT34	WTG	N 41.0191225	W - 70.5493824
AT35	WTG	N 41.0194164	W - 70.5273630
AT36	WTG	N 41.0197062	W - 70.5053432
AT37	WTG	N 41.0199917	W - 70.4833231
AT38	WTG	N 41.0202731	W - 70.4613027
AT39	WTG	N 41.0205502	W - 70.4392819
AT40	WTG	N 41.0208231	W - 70.4172609
AT41	WTG	N 41.0210918	W - 70.3952396
AU36	WTG	N 41.0030287	W - 70.5049636
AU37	WTG	N 41.0033141	W - 70.4829490
AU38	WTG	N 41.0035953	W - 70.4609341
AU39	WTG	N 41.0038722	W - 70.4389190
AU40	WTG	N 41.0041450	W - 70.4169035
AV37	WTG	N 40.9866364	W - 70.4825752
AV38	WTG	N 40.9869174	W - 70.4605659
AV39	WTG	N 40.9871942	W - 70.4385563
AW38	WTG	N 40.9702395	W - 70.4601980

When enforced, no unauthorized vessel or person would be permitted to enter the safety zone without obtaining permission from the First Coast Guard District Commander or a designated representative. Requests for entry into the safety zone would be considered and reviewed on a case-by-case basis. Persons or vessels seeking to enter the safety zone must request authorization from the First Coast Guard District Commander or designated representative via VHF-FM channel 16 or by phone at 617-603-1560 (First Coast Guard District Command Center). If permission is granted, all persons and vessels shall comply with the instructions of the First Coast Guard District Commander or designated representative.

The regulatory text appears at the end of this document.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and

Executive orders related to rulemaking. A summary of our analyses based on these statutes and Executive orders follows.

A. Regulatory Planning and Review

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

Aligning with 33 CFR 147.15, the established safety zones will extend to a maximum distance of 500-meters around the OCS facility measured from its center point. Vessel traffic will be able to safely transit around the safety zones, which would impact a small,

designated area in the Atlantic Ocean, without significant impediment to their voyage. This safety zone will provide for the safety of life, property, and the environment during the construction of each structure, in accordance with Coast Guard maritime safety missions.

B. Impact on Small Entities

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

economic impact on a substantial number of small entities.

This rule may affect owners or operators of vessels intending to transit or anchor in the VW1WF, some of which might be small entities. However, these safety zones will not have a significant economic impact on a substantial number of these entities because they are temporarily enforced, allow for deviation requests, and do not impact vessel transit significantly. Regarding the enforcement period, although these safety zones will be in effect from June 27, 2023, through May 31, 2024, vessels will only be prohibited from the regulated zone during periods of actual construction activity in correspondence to the period of enforcement. We expect the enforcement period at each location to last approximately 48 hours as construction progresses from one structure location to the next throughout the mixed phases. Additionally, vessel traffic could pass safely around each safety zone using an alternate route. Use of an alternate route likely will cause minimal delay for the vessel in reaching their destination depending on other traffic in the area and vessel speed. Vessels will also be able to request deviation from this rule to transit through a safety zone. Such requests would be considered on a case by-case basis and may be authorized by the First Coast Guard District Commander or a designated representative. For these reasons, the Coast Guard expects any impact of this rulemaking establishing a temporary safety zone around these OCS facilities to be minimal and have no significant economic impact on small entities.

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The

Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this final rule under Department of Homeland

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

G. Protest Activities

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

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (waters).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 544; 43 U.S.C. 1333; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 147.T01–0277 to read as follows:

§ 147.T01–0277 Safety Zones; Vineyard Wind 1 Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0501, Offshore Massachusetts, Atlantic Ocean.

(a) *Description.* The area within 500-meters of the center point of the positions provided in the following table is a safety zone:

TABLE 1 TO PARAGRAPH (a)

Name	Facility type	Latitude	Longitude
AL38	WTG	N 41.1370161	W – 70.4638911
AM37	ESP	N 41.1200616	W – 70.4851682
AM38	WTG	N 41.1203387	W – 70.4635204
AM39	WTG	N 41.1206168	W – 70.4414663
AN36	WTG	N 41.1030927	W – 70.5072461
AN37	WTG	N 41.1033791	W – 70.4851982
AN38	WTG	N 41.1036612	W – 70.4631500
AN39	WTG	N 41.1039392	W – 70.4411014
AP35	WTG	N 41.0861251	W – 70.5289069
AP36	WTG	N 41.0864155	W – 70.5068649
AP37	WTG	N 41.0867017	W – 70.4848226
AP38	WTG	N 41.0869837	W – 70.4627799
AP39	WTG	N 41.0872615	W – 70.4407369
AP40	WTG	N 41.0875351	W – 70.4186937
AP41	WTG	N 41.0878044	W – 70.3966501
AQ34	WTG	N 41.0691535	W – 70.5505566
AQ35	WTG	N 41.0694480	W – 70.5285205
AQ36	WTG	N 41.0697382	W – 70.5064840
AQ37	WTG	N 41.0700243	W – 70.4844472
AQ38	WTG	N 41.0703061	W – 70.4624101
AQ39	WTG	N 41.0705837	W – 70.4403727
AQ40	WTG	N 41.0708571	W – 70.4183350
AQ41	WTG	N 41.0711263	W – 70.3962970
AQ42	WTG	N 41.0713913	W – 70.3742587
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AR34	WTG	N 41.0524766	W – 70.5501649
AR35	WTG	N 41.0527709	W – 70.5281343
AR36	WTG	N 41.0530609	W – 70.5061034
AR37	WTG	N 41.0533468	W – 70.4840722
AR38	WTG	N 41.0536285	W – 70.4620407
AR39	WTG	N 41.0539059	W – 70.4400088
AR40	WTG	N 41.0541792	W – 70.4179767
AR41	WTG	N 41.0544482	W – 70.3959442
AR42	WTG	N 41.0547130	W – 70.3739115
AS32	WTG	N 41.0351987	W – 70.5938225
AS33	WTG	N 41.0355012	W – 70.5717982
AS34	WTG	N 41.0357995	W – 70.5497735
AS35	WTG	N 41.0360937	W – 70.5277485
AS36	WTG	N 41.0363836	W – 70.5057231
AS37	WTG	N 41.0366693	W – 70.4836975
AS38	WTG	N 41.0369508	W – 70.4616715
AS39	WTG	N 41.0372281	W – 70.4396452
AS40	WTG	N 41.0375012	W – 70.4176186
AS41	WTG	N 41.0377701	W – 70.3955918
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AT36	WTG	N 41.0197062	W – 70.5053432
AT37	WTG	N 41.0199917	W – 70.4833231
AT38	WTG	N 41.0202731	W – 70.4613027
AT39	WTG	N 41.0205502	W – 70.4392819
AT40	WTG	N 41.0208231	W – 70.4172609
AT41	WTG	N 41.0210918	W – 70.3952396
AU36	WTG	N 41.0030287	W – 70.5049636
AU37	WTG	N 41.0033141	W – 70.4829490
AU38	WTG	N 41.0035953	W – 70.4609341
AU39	WTG	N 41.0038722	W – 70.4389190
AU40	WTG	N 41.0041450	W – 70.4169035
AV37	WTG	N 40.9866364	W – 70.4825752
AV38	WTG	N 40.9869174	W – 70.4605659
AV39	WTG	N 40.9871942	W – 70.4385563
AW38	WTG	N 40.9702395	W – 70.4601980

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer

operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the First Coast Guard District Commander in the enforcement of the safety zones.

(c) *Regulations.* No vessel may enter or remain in the safety zones described in paragraph (a) of this section except for the following:

(1) An attending vessel as defined in § 147.20; and

(2) A vessel authorized by the First Coast Guard District Commander or a designated representative.

(d) *Request for permission.* Persons or vessels seeking to enter the safety zone must request authorization from the First Coast Guard District Commander or a designated representative. If permission is granted, all persons and vessels must comply with lawful instructions of the First Coast Guard District Commander or designated representative via VHF–FM channel 16 or by phone at 617–223–1560 (First Coast Guard District Command Center).

(e) *Effectiveness and enforcement periods.* This section is in effect from June 27, 2023, through 11:59 p.m. on May 31, 2024. But it will only be enforced during active construction or other instances which may cause a hazard to navigation deemed necessary by the First Coast Guard District Commander. The First Coast Guard District Commander will make notification of the exact dates and times in advance of each enforcement period for the locations in paragraph (a) of this section to the local maritime community through the Local Notice to Mariners and will issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency. If the project is completed before May 31, 2024, enforcement of the safety zones will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at <https://www.navcen.uscg.gov>.

Dated: June 27, 2023.

J.W. Mauger,

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

[FR Doc. 2023–14073 Filed 6–29–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0518]

RIN 1625–AA00

Safety Zone; Savannah River 4th of July Fireworks Show, Savannah, GA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

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

the waters surrounding the Savannah River in Savannah, Georgia, during the July 4th Fireworks event. The safety zone is necessary to ensure the safety of participant vessels, spectators, and the general public during the event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Savannah or a designated representative.

DATES: This rule is effective from 9 p.m. until 11 p.m., on July 4, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2023–0518 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Alex McConnell, Waterways Management Division, Marine Safety Unit Savannah, U.S. Coast Guard; telephone 912–652–4353, extension 240, email Alexander.W.McConnell@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The Coast Guard did not receive final details of the event until June 8, 2023, and the event is scheduled to take place on July 4, 2023. The event would begin before the rulemaking process would be completed. Because of the dangers posed by the fireworks display, a safety zone is necessary without delay to

ensure the safety of persons, vessels, and the marine environment. It is impracticable and contrary to the public interest to delay this rule because it is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks display.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with a fireworks display adjacent to a major shipping channel.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Savannah (COTP) has determined that potential hazards with the Savannah River July 4th Fireworks event near downtown Savannah, GA. This rule is necessary to ensure the safety of the event participants, the general public, vessels and the navigable waters of Marathon, Florida, during the Savannah River July 4th Fireworks event.

IV. Discussion of the Rule

This rule establishes a safety zone on all navigable waters in the Savannah River adjacent to downtown Savannah, GA, during the Savannah River, July 4th Fireworks event. The safety zone will be enforced from 9 p.m. to 11 p.m. on July 4, 2023. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fallout from the July 4th Fireworks display. No person or vessel will be permitted to enter, transit through, anchor in, or remain within the safety zone without obtaining permission from the COTP or a designated representative. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted by the COTP or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP or a designated representative. The Coast Guard will provide notice of the safety zone by Broadcast Notice to Mariners, and/or by on-scene designated representatives.

V. Regulatory Analyses

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

Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

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

This regulatory action determination is based on the location, duration, and time-of-day of the safety zone. This rule involves a safety zone that will prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within a limited area on the navigable waters of the Savannah River, Savannah, GA, during a firework display lasting thirty minutes. Although persons and vessels may not enter, transit through, anchor in, or remain within the zone without authorization from the COTP or a designated representative, they will be able to safely transit around the safety zone. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business,

organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule

will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within a limited area on the navigable waters of the Savannah River, Savannah, GA during a firework display lasting thirty minutes. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T07–0138 to read as follows:

§ 165.T07–0138 Safety Zone; 4th of July Fireworks Show, Savannah River, Savannah, GA.

(a) *Location.* The following area is a safety zone: All waters of the Savannah River, from surface to bottom, bounded by a line drawn from a point located at 32°05'04" N, 081°05'46" W, thence to 32°05'10" N, 081°05'39" W, thence to 32°05'04" N, 081°05'30" W, thence to 32°04'57" N, 081°05'34" W.

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

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

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the COTP by telephone at 912–247–0073, or a designated representative via VHF–FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP Savannah or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners via VHF–FM channel 16, and/or by on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced from 9 p.m. until 11 p.m. on July 4, 2023.

Dated: June 23, 2023.

Kevin A. Broyles,

Commander, U.S. Coast Guard, Captain of the Port Savannah.

[FR Doc. 2023–13886 Filed 6–29–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2023–0424]

Safety Zone; Annual Fireworks Displays and Other Events in the Eighth Coast Guard District Requiring Safety Zones—Madisonville Old Fashioned 4th of July

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Madisonville Old Fashioned 4th of July fireworks display located on the navigable waters of the Tchefuncte River, in front of the Madisonville Town Hall. Our regulation for marine events within the Eighth Coast Guard District Sector New Orleans Annual and Recurring Safety Zones identifies the regulated area for this event. This action is necessary to provide for the safety of life on these navigable waterways during the event. During the enforcement period, entry into this safety zone into this zone is prohibited unless authorized by the Captain of the Port or a designated representative.

DATES: The regulations in 33 CFR 165.801, will be enforced for the location identified in Item 15 of Table 5 to § 165.801, from 8 p.m. through 9 p.m. on July 4, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Commander William Stewart, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2246, email William.A.Stewart@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.801, Table 5 to § 165.801, item 15 for the Madisonville Old Fashioned 4th of July fireworks display event. This safety will be enforced from 8 p.m. through 9 p.m. on July 4, 2023. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for annual fireworks displays and other events in Sector New Orleans Annual and Recurring Safety Zones in § 165.801, Table 5 to § 165.801, Item 15, specifies the approximate location of the regulated area on the Tchefuncte River, in front of the Madisonville Town Hall. During the enforcement period, as reflected in § 165.801(a), entry into this safety zone is prohibited unless

authorized by the Captain of the Port or a designated representative.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via Marine Safety Information Bulletin and Broadcast Notice to Mariners.

Dated: June 24, 2023.

K.K. Denning,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2023–13887 Filed 6–29–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 38

RIN 2900–AR36

Allowances for Caskets and Urns for Unclaimed Remains of Veterans

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is implementing in regulation the Charles Duncan Buried with Honor Act of 2016, which expanded the casket and urn authority to apply to eligible veteran burials in State and Tribal cemeteries that received a VA cemetery grant. In addition, VA is establishing flat-rate allowances for caskets and urns, which will be adjusted annually based on the Consumer Price Index (CPI). Additionally, VA is updating the specifications for caskets based on feedback from funeral directors and other funeral industry professionals. Finally, VA is eliminating the retroactive reimbursement provisions since the relevant applicability period has passed.

DATES: This rule is effective July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Daniel Catron, Supervisory Program Analyst, National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; Daniel.Catron@va.gov, telephone: (314) 416–6324 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On December 8, 2022, VA published a proposed rule in the **Federal Register** (87 FR 75196) that proposed to implement the following: expansion of the casket and urn authority to apply to eligible veteran burials in State and Tribal cemeteries that received a VA cemetery grant; flat-rate allowances for

caskets and urns; updated specifications for caskets; and the elimination of retroactive reimbursement provisions. The public comment period ended on February 6, 2023, and VA received 3 comments in response to the proposed rule.

One comment was not relevant to this rulemaking and indicated an individual preference for memorialization. VA considers this preferential request to be beyond the scope of this rulemaking and will make no changes to the regulatory text based on this comment.

Another commenter expressed support for the proposed rule. The commenter commended VA's continued engagement and outreach to funeral homes and funeral directors regarding the casket and urn reimbursement program rates. The commenter applauded the payment of flat-rate allowances for caskets and urns, noting consistency of this programmatic approach with other VA burial benefits. The commenter agreed with VA that the flat-rate provision would provide a predictable methodology for determining casket and urn reimbursement. The commenter supported VA's approach and intent to avoid confusion regarding the "actual cost" standard that required that actual costs be shown by invoices reflecting the purchase price of the casket or urn purchased by the individual or entity requesting reimbursement. The commenter expressed support for the elimination of the outdated retroactive applicability provision and support for the programmatic expansion of the casket and urn benefit for qualifying burials in Veterans' cemeteries that received VA grant funds. VA appreciates the commenter's support for the proposed changes to implement the casket and urn benefit. VA will make no changes to the regulatory text based on this comment.

Finally, VA received a comment that expressed general support of VA programs that ensure respect for deceased veterans, regardless of whether they have a next-of-kin. VA appreciates the commenter's recognition of our commitment to ensuring veterans who die without family members to see to their last wishes still receive a dignified burial. We also acknowledge the commenter's expressed concern and opposition to the proposed flat-rate allowance for caskets and urns due to varying prices that may cause potential resource shortfalls. However, VA declines to make any changes to the regulatory text based on this comment.

To the extent the commenter had concerns that individuals and organizations would not utilize the

program due to the allowance potentially not covering all costs, as stated in the proposed rule, in § 38.628(e), VA will make cost-of-living adjustments for the flat-rate allowances using the CPI, which is a methodology used in other, similar VA monetary allowances. Consistent with the Veterans Benefits Administration (VBA) cost increases for monetary allowances under 38 U.S.C. 2303, from June to June each year, under this rule the National Cemetery Administration (NCA) will apply a similar percentage increase (rounded to the nearest dollar) to the allowances for caskets and urns. Use of VBA's cost-of-living increase analysis will promote consistency across VA benefit programs and ensure the casket and urn allowances meet current costs, to the extent practicable. Also, as noted in the proposed rule, "[t]he purpose of the casket and urn reimbursement is to help offset a claimant's cost for bringing unclaimed veterans' remains to burial in a VA national or grant-funded cemetery" and to avoid a significant financial loss or gain for an individual or entity for having made the purchase, 87 FR at 75198, not necessarily to make each individual or entity completely whole for the purchase.

To the extent the commenter had concerns that the Government may not have resources to administer the program and provide caskets and urns for all eligible veterans, 38 U.S.C. 2306(f) authorizes VA to furnish a casket or urn for burial of the unclaimed remains of veterans for whom VA cannot identify the next of kin and determines that sufficient resources for the furnishing of a casket or urn for burial are not available. The implementation of flat-rate allowances will not jeopardize funding of the casket and urn reimbursement program. The program is funded through the VBA Compensation and Pension mandatory appropriation. As such, the appropriation does not constrain the payment of benefits. If a Veteran or survivor is eligible for a benefit, it is paid. As we noted in the proposed rule, we believe using flat-rate allowances will promote consistency and efficiency in the administration of this program. VA appreciates the commenter's concerns but will make no changes to the regulatory text based on this comment.

Executive Orders 12866, 13563 and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Executive Order on Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review). The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866, as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612, because the number of claims and the amounts involved are expected to be small. The average cost of a burial receptacle that meets regulatory specifications under this rule is \$1,199 for caskets and \$138 for urns in 2023. Also, we estimate that the total number of allowances for 2023 will be 259 for caskets and 18 for urns. Because the rulemaking provides for issuance of an allowance, the individual or entity purchasing the burial receptacle is only entitled to recoup the allowance rate, regardless of the actual purchase price.

Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no

such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

Although this action contains provisions constituting collections of information at 38 CFR 38.628, under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new collection of information is associated with this final rule. This rulemaking creates no change to the annual PRA costs of the program. The information collection requirements for 38 CFR 38.628 are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 2900–0799. VA made non-substantive text changes to an existing form (VA40–10088) to reflect programmatic updates that will not affect the information collection burden costs or create administrative costs associated with this rulemaking.

Assistance Listing

The Assistance Listing number and title for the programs affected by this document is 64.205, VA Casket or Urn Reimbursement Program.

Congressional Review Act

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

List of Subjects in 38 CFR Part 38

Administrative practice and procedure, Cemeteries, Claims, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on May 3, 2023, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 38 as set forth below:

PART 38—NATIONAL CEMETERIES OF THE DEPARTMENT OF VETERANS AFFAIRS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 38 U.S.C. 107, 501, 512, 2306, 2400, 2402, 2403, 2404, 2407, 2408, 2411, 7105.

■ 2. Amend § 38.628 by revising the section heading, the introductory text of paragraphs (a) and (c), and paragraphs (c)(1), (c)(5)(i), (d), and (e) to read as follows:

§ 38.628 Allowance for caskets and urns for unclaimed remains of veterans.

(a) VA will issue a flat-rate allowance, as established in paragraph (d) of this section, to any individual or entity for a casket or urn, purchased by the individual or entity for the burial in a national cemetery or in a veterans' cemetery of a State or Tribal Organization that has received a grant under 38 U.S.C. 2408, of an eligible deceased veteran for whom VA:

* * * * *

(c) An individual or entity may request an allowance from VA under paragraph (a) of this section by completing and submitting VA Form 40–10088 and supporting documentation, in accordance with the instructions on the form. Prior to approving issuance of an allowance, VA must find all of the following:

(1) The veteran is eligible for burial in a VA national cemetery or in a veterans' cemetery of a State or Tribal Organization that has received a grant under 38 U.S.C. 2408;

* * * * *

(5) * * *

(i) Caskets must be of metal construction of at least 20-gauge thickness, designed for containing human remains, sufficient to contain the remains of the deceased veteran, and include external fixed rails or swing arm handles.

* * * * *

(d) The allowance for a claim received in any calendar year under paragraph (a) of this section is \$1,199.00 for a metal casket and \$138.00 for an urn of durable material.

(e) VA will make cost-of-living adjustments for the flat-rate casket and urn allowances using the Consumer Price Index (CPI). Each fiscal year, VA will provide a percentage increase (rounded to the nearest dollar) in the casket and urn flat-rate allowances equal to the percentage by which the CPI (all items, United States city average) for the 12-month period (June to June) preceding the beginning of the fiscal year for which the percentage increase is made exceeds the CPI for the 12-month period preceding the 12-month period described in this paragraph (e). VA will only make cost-

of-living increases to the flat rate allowances when the CPI has increased.

* * * * *

[FR Doc. 2023–13712 Filed 6–29–23; 8:45 am]

BILLING CODE 8320–01–P

POSTAL SERVICE

39 CFR Part 111

Priority Mail Express Refunds

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is amending *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM®) to discontinue Priority Mail Express® postage refunds for guaranteed service for Alaska and Hawaii.

DATES: Effective August 1, 2023.

FOR FURTHER INFORMATION CONTACT: Catherine Knox at (202) 268–5636 or Garry Rodriguez at (202) 268–7281.

SUPPLEMENTARY INFORMATION: On May 23, 2023, the Postal Service published a notice of proposed rulemaking (88 FR 33066) to discontinue Priority Mail Express postage refunds for guaranteed service for Alaska and Hawaii. The Postal Service did not receive any formal comments.

The Postal Service has determined that operationally we cannot meet the service commitments for Priority Mail Express expected by customers for Alaska and Hawaii.

As a result, the Postal Service is discontinuing postage refunds for guaranteed service for Priority Mail Express pieces destined to or originating from Alaska or Hawaii. Postage refunds for loss will still be available for pieces destined to or originating from Alaska or Hawaii.

We believe this revision will provide customers with a more efficient mailing experience.

The Postal Service adopts the described changes to *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations*. We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

604 Postage Payment Methods and Refunds

* * * * *

9.0 Exchanges and Refunds

* * * * *

9.5 Priority Mail Express Postage and Fees Refunds

* * * * *

9.5.5 Refunds Not Given

Postage will not be refunded if the guaranteed service was not provided due to any of the following circumstances:

* * * * *

[Renumber items i and j as j and k, and add new item i to read as follows:]

i. The postage refund requested is other than for loss, and the Priority Mail Express piece was destined to or originated from Alaska or Hawaii.

* * * * *

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–13942 Filed 6–29–23; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0036; FRL–10790–02–R9]

Air Plan Revisions; California; Sacramento Metropolitan Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to partially approve and partially disapprove a revision to the Sacramento Metropolitan Air Quality Management District (SMAQMD) portion of the California State Implementation Plan (SIP). The revision concerns the SMAQMD’s demonstration regarding reasonably available control technology (RACT) requirements and negative declarations for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or “standards”) in the portion of the Sacramento Metropolitan nonattainment area under the jurisdiction of the SMAQMD. We are also correcting sections in the Code of Federal Regulations (CFR) to reflect the current status of certain provisions of the SMAQMD portions of the California SIP related to the 1997 8-hour ozone NAAQS.

DATES: This rule is effective July 31, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2023–0036. 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. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT:

Eugene Chen, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4304 or by email at chen.eugene@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to the EPA.

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Statutory and Executive Order Reviews

I. Proposed Action

On April 5, 2023 (88 FR 20086), the EPA proposed to partially approve and partially disapprove the California Air Resources Board’s (CARB) submittals of the SMAQMD’s 2017 RACT SIP for the 2008 Ozone National Ambient Air Quality Standards (NAAQS), as listed in Table 1 below.

TABLE 1—SUBMITTED DOCUMENTS

Local agency	Document	Adopted	Submitted
SMAQMD	Demonstration of Reasonably Available Control Technology for the 2008 Ozone National Ambient Air Quality Standard (NAAQS) (“2017 RACT SIP”).	03/23/2017	05/05/2017

We proposed to partially approve SMAQMD’s 2017 RACT SIP and negative declarations because we determined that, except for the RACT element for non-CTG major sources of NO_x, they complied with the relevant CAA requirements. We proposed to partially disapprove SMAQMD’s 2017 RACT SIP because several of the District

rules relied upon to implement RACT for non-CTG major sources of NO_x contain provisions that are not consistent with EPA’s Startup, Shutdown, and Malfunction (SSM) Policy. District Rule 413 (Stationary Gas Turbines) contains a provision that explicitly exempts affected units from complying with rule standards during

periods of startup and shutdown and does not provide for an alternative emissions limitation during such periods. District Rule 411 (NO_x from Boilers, Process Heaters, and Steam Generators) and Rule 419 (NO_x from Miscellaneous Combustion Units) both contain monitoring provisions that preclude the use of specified data for

compliance determinations during periods of startup and shutdown. As discussed in greater detail in our proposed action, the provisions in these three rules are inconsistent with EPA policy and Clean Air Act requirements, and represent the basis for our partial disapproval.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted on the proposed action, and there is no change to our assessment of the SIP submittals as described in our proposed action. Therefore, as authorized in section

110(k)(3) of the Act, the EPA is partially disapproving SMAQMD's 2017 RACT SIP with respect to the RACT element for the 2008 ozone NAAQS for non-CTG major sources of NO_x, and partially approving the remainder of SMAQMD's 2017 RACT SIP and negative declarations as meeting the RACT requirement for the 2008 ozone NAAQS for the remaining categories. Table 2 summarizes our final action on the RACT elements for the 2008 ozone NAAQS.

TABLE 2—LIST OF RACT ELEMENTS—2008 OZONE NAAQS

CTG document No.	RACT element	District rule implementing RACT	Negative declaration submitted	EPA final action
EPA-450/R-75-102	Design Criteria for Stage I Vapor Control—Gasoline Service Stations.	448 (Gasoline Transfer Into Stationary Storage Containers).		Approval.
EPA-450/2-77-008	Surface Coating of Cans	452 (Can Coating)		Approval.
EPA-450/2-77-008	Surface Coating of Coils		Yes	Approval.
EPA-450/2-77-008	Surface Coating of Paper		Yes	Approval.
EPA-450/2-77-008	Surface Coating of Fabric		Yes	Approval.
EPA-450/2-77-008	Surface Coating of Automobiles and Light-Duty Trucks.		Yes	Approval.
EPA-450/2-77-022	Solvent Metal Cleaning	454 (Degreasing Operations)		Approval.
EPA-450/2-77-025	Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.		Yes	Approval.
EPA-450/2-77-026	Tank Truck Gasoline Loading Terminals	447 (Organic Liquid Loading)		Approval.
EPA-450/2-77-032	Surface Coating of Metal Furniture	451 (Surface Coating of Miscellaneous Metal Parts and Products).		Approval.
EPA-450/2-77-033	Surface Coating of Insulation of Magnet Wire.		Yes	Approval.
EPA-450/2-77-034	Surface Coating of Large Appliances		Yes	Approval.
EPA-450/2-77-035	Bulk Gasoline Plants	447 (Organic Liquid Loading)		Approval.
EPA-450/2-77-036	Storage of Petroleum Liquids in Fixed-Roof Tanks.	446 (Storage of Petroleum Products)		Approval.
EPA-450/2-77-037	Cutback Asphalt	453 (Cutback and Emulsified Asphalt Paving Materials).		Approval.
EPA-450/2-78-015	Surface Coating of Miscellaneous Metal Parts and Products.	451 (Surface Coating of Miscellaneous Metal Parts and Products).		Approval.
EPA-450/2-78-029	Manufacture of Synthesized Pharmaceutical Products.	464 (Organic Chemical Manufacturing Operations).		Approval.
EPA-450/2-78-030	Manufacture of Pneumatic Rubber Tires		Yes	Approval.
EPA-450/2-78-032	Factory Surface Coating of Flat Wood Paneling.		Yes	Approval.
EPA-450/2-78-033	Graphic Arts—Rotogravure and Flexography.	450 (Graphic Arts Operations)—Flexography only.	Yes—Rotogravure only.	Approval.
EPA-450/2-78-036	Leaks from Petroleum Refinery Equipment		Yes	Approval.
EPA-450/2-78-047	Petroleum Liquid Storage in External Floating Roof Tanks.	446 (Storage of Petroleum Products)		Approval.
EPA-450/2-78-051	Leaks from Gasoline Tank Trucks and Vapor Collection Systems.	447 (Organic Liquid Loading); 448 (Gasoline Transfer Into Stationary Storage Containers).		Approval.
EPA-450/3-82-009	Large Petroleum Dry Cleaners		Yes	Approval.
EPA-450/3-83-006	Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.	443 (Leaks from Synthetic Organic Chemical and Polymer Manufacturing).		Approval.
EPA-450/3-83-007	Leaks from Natural Gas/Gasoline Processing Plants.		Yes	Approval.
EPA-450/3-83-008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.		Yes	Approval.
EPA-450/3-84-015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.		Yes	Approval.
EPA-450/4-91-031	Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.	464 (Organic Chemical Manufacturing Operations).		Approval.
EPA-453/R-96-007	Wood Furniture Manufacturing Operations ..		Yes	Approval.
EPA-453/R-94-032; 61 FR 44050; 8/27/96.	ACT Surface Coating at Shipbuilding and Ship Repair Facilities; Shipbuilding and Ship Repair Operations (Surface Coating).		Yes	Approval.
EPA-453/R-97-004; 59 FR 29216; 6/06/94.	Aerospace MACT and Aerospace (CTG & MACT).		Yes	Approval.
EPA-453/R-06-001	Industrial Cleaning Solvents	466 (Solvent Cleaning)		Approval.
EPA-453/R-06-002	Offset Lithographic Printing and Letterpress Printing.	450 (Graphic Arts Operations)		Approval.
EPA-453/R-06-003	Flexible Package Printing	450 (Graphic Arts Operations)		Approval.
EPA-453/R-06-004	Flat Wood Paneling Coatings		Yes	Approval.
EPA 453/R-07-003	Paper, Film, and Foil Coatings		Yes	Approval.

TABLE 2—LIST OF RACT ELEMENTS—2008 OZONE NAAQS—Continued

CTG document No.	RACT element	District rule implementing RACT	Negative declaration submitted	EPA final action
EPA 453/R-07-004	Large Appliance Coatings		Yes	Approval.
EPA 453/R-07-005	Metal Furniture Coatings	451 (Surface Coating of Miscellaneous Metal Parts and Products).		Approval.
EPA 453/R-08-003	Miscellaneous Metal Parts Coatings; Table 2—Metal Parts and Products.	451 (Surface Coating of Miscellaneous Metal Parts and Products).		Approval.
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings; Table 3—Plastic Parts and Products.	468 (Surface Coating of Plastic Parts and Products).		Approval.
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings; Table 4—Automotive/Transportation and Business Machine Plastic Parts.	468 (Surface Coating of Plastic Parts and Products).		Approval.
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings; Table 5—Pleasure Craft Surface Coating.		Yes	Approved November 19, 2020 (85 FR 73640). ^a
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings; Table 6—Motor Vehicle Materials.	459 (Automotive, Truck, and Heavy Equipment Refinishing Operations).		Approval.
EPA 453/R-08-004	Fiberglass Boat Manufacturing Materials		Yes	Approval.
EPA 453/R-08-005	Miscellaneous Industrial Adhesives		Yes	Approval.
EPA 453/R-08-006	Automobile and Light-Duty Truck Assembly Coatings.		Yes	Approval.
	Non-CTG Major Sources of NO _x	411 (NO _x from Boilers, Process Heaters, and Steam Generators); 412 (Stationary Internal Combustion Engines); 413 (Stationary Gas Turbines); 419 (NO _x from Miscellaneous Combustion Units).		Disapproval. ^b
	Non-CTG Major Sources of VOC	Source-specific Requirements		Approval.

^a The regulatory text for the Code of Federal Regulations (CFR) associated with our November 19, 2020 approval did not specify that the approval pertained to the 2008 8-hour ozone NAAQS. The state's submittal, however, is clear that its negative declaration was for the 2008 8-hour ozone NAAQS and was adopted and submitted in part to stop sanctions clocks associated with our February 3, 2017 Finding of Failure to Submit a RACT demonstration for that NAAQS (82 FR 9158). In the CFR text for this final action, we are removing any ambiguity by clarifying that our 2020 approval addressed the 2008 8-hour ozone NAAQS.

^b As described in greater detail in our Technical Support Document (Docket Item B-01), our disapproval for the non-CTG major sources of NO_x element is based in the deficiencies noted in Rules 411 and 413, as well as the lack of SIP-approved RACT level controls for the Mitsubishi Chemical and Carbon Fiber Composites facility due to the deficiencies noted in the submitted version of Rule 419.

We are also correcting an error in the CFR concerning previous disapprovals for SMAQMD's 2006 RACT SIP for the 1997 8-hour ozone NAAQS that are codified in 40 CFR 52.237(b)(1)(i). SMAQMD has since addressed these disapprovals, but in our rulemakings approving SMAQMD's submittals to address these disapprovals, we failed to remove the language in the CFR that codified the disapprovals, which could result in public confusion about the status of the California SIP.

On December 4, 2017, the EPA published two final rules entitled "Approval of California Air Plan Revisions, Sacramento Metropolitan Air Quality Management District" (82 FR 57123 and 82 FR 57130) which approved revisions to the SMAQMD portion of the California SIP. The approved revisions fixed the deficiencies identified in our partial disapproval of SMAQMD's 2006 RACT SIP for the 1997 8-hour ozone NAAQS (81 FR 53280, August 12, 2016) with respect to the requirement to establish RACT-level controls for sources covered by the pharmaceutical products manufacturing category, as well as source-specific VOC requirements for the Kiefer Landfill. However, the EPA's final rules inadvertently failed to include amendatory instructions to remove these identified elements from

the regulatory text at 40 CFR 52.237(b)(1)(i), where they are listed as disapproved elements of SMAQMD's 2006 RACT SIP. This action corrects the regulatory text to reflect the current status of SMAQMD's RACT obligations for the 1997 8-hour ozone NAAQS.

The EPA has determined that this action to correct the regulatory text related to these disapprovals falls under the "good cause" exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding "good cause," authorizes agencies to dispense with public participation where public notice and comment procedures are impracticable, unnecessary, or contrary to public interest. Public notice and comment for this action to correct regulatory text is unnecessary because the underlying rules were already subject to a 30-day comment period, the final actions on these rules state that the deficiencies were cured, and this action is merely updating the regulatory text accordingly. Further, this action is consistent with the purpose and rationale of the final rules. Because this action does not change the EPA's analyses or overall actions, no purpose would be served by additional public notice and comment. Consequently, additional public notice and comment are unnecessary.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provision of the Act and applicable federal regulations. 42 U.S.C. 740(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to review state choices, and approve those choices if they meet the minimum criteria of the Act. Accordingly, this final action partially approves and partially disapproves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law.

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

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not

impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

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

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

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

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

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

The District did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goals of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

K. Congressional Review Act (CRA)

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

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 29, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

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

Dated: June 22, 2023.

Martha Guzman Aceves,
Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations 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 F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(599) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(599) The following plan was submitted on May 5, 2017, by the Governor’s designee as an attachment to a letter dated May 5, 2017.

(i) [Reserved]

(ii) *Additional Materials.*

(A) Sacramento Metropolitan Air Quality Management District.

(1) Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) for the 2008 8-Hour Ozone National Ambient Air Quality Standards (NAAQS) (“Demonstration of Reasonably Available Control Technology for the 2008 Ozone NAAQS”), as adopted on March 23, 2017, except the RACT

determination for non-CTG major sources of NO_x.

(2) [Reserved]

* * * * *

■ 3. Section 52.222 is amended by revising paragraph (a)(2)(v) to read as follows:

§ 52.222 Negative declarations.

* * * * *

(a) * * *

(2) * * *

(v) The following negative declarations for the 2008 ozone NAAQS were adopted by the Sacramento Metropolitan Air Quality Management District.

CTG document No.	Title	Adopted: 3/22/2018 Submitted: 6/11/2018 SIP approved: 11/19/2020	Adopted: 3/23/2017 Submitted: 5/5/2017 SIP approved: 6/30/2023
(A) EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources— Volume II: Surface Coating of Coils.		X
(B) EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources— Volume II: Surface Coating of Paper.		X
(C) EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources— Volume II: Surface Coating of Fabrics.		X
(D) EPA-450/2-77-008	Control of Volatile Organic Emissions from Existing Stationary Sources— Volume II: Surface Coating of Automobiles and Light-Duty Trucks.		X
(E) EPA-450/2-77-025	Control of Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.		X
(F) EPA-450/2-77-033	Control of Volatile Organic Emissions from Existing Stationary Sources— Volume IV: Surface Coating of Insulation of Magnet Wire.		X
(G) EPA-450/2-77-034	Control of Volatile Organic Emissions from Existing Stationary Sources— Volume V: Surface Coating of Large Appliances.		X
(H) EPA-450/2-78-030	Manufacture of Pneumatic Rubber Tires		X
(I) EPA-450/2-78-032	Factory Surface Coating of Flat Wood Paneling		X
(J) EPA-450/2-78-033	Graphic Arts—Rotogravure and Flexography (Rotogravure only)		X
(K) EPA-450/2-78-03	Leaks from Petroleum Refinery Equipment		X
(L) EPA-450/3-82-009	Large Petroleum Dry Cleaners		X
(M) EPA-450/3-83-007	Leaks from Natural Gas/Gasoline Processing Plants		X
(N) EPA-450/3-83-008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.		X
(O) EPA-450/3-84-015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing In- dustry.		X
(P) EPA-453/R-94-032	Alternative Control Technology Document—Surface Coating Operations at Shipbuilding and Ship Repair Facilities. Shipbuilding and Ship Repair Operations (Surface Coating), <i>see the Fed- eral Register</i> of 08/27/96.		X
(Q) EPA-453/R-97-004	Control of Volatile Organic Compound Emissions from Coating Operations at Aerospace Manufacturing and Rework Operations. Aerospace MACT, <i>see the Federal Register</i> of 06/06/94.		X
(R) EPA-453/R-06-004	Flat Wood Paneling Coatings		X
(S) EPA 453/R-07-003	Paper, Film, and Foil Coatings		X
(T) EPA 453/R-07-004	Large Appliance Coatings		X
(U) EPA 453/R-08-003	Miscellaneous Metal and Plastic Parts Coatings (Table 5—Pleasure Craft Surface Coating).	X	
(V) EPA 453/R-08-004	Fiberglass Boat Manufacturing Materials		X
(W) EPA 453/R-08-005	Miscellaneous Industrial Adhesives		X
(X) EPA 453/R-08-006	Automobile and Light-Duty Truck Assembly Coatings		X

* * * * *

■ 4. Section 52.237 is amended by removing and reserving paragraph (b)(1)(i), and adding paragraph (b)(1)(iii) to read as follows:

§ 52.237 Part D disapproval.

* * * * *

(b) * * *

(1) * * *

(iii) RACT determination for non-CTG major sources of Nitrogen Oxides (NO_x) for the 2008 ozone NAAQS, as contained in the submittal titled “Demonstration of Reasonably Available

Control Technology for the 2008 Ozone NAAQS”, as adopted on March 23, 2017, and submitted on May 5, 2017.

* * * * *

[FR Doc. 2023-13744 Filed 6-29-23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2018-0160; FRL-10867-02-R9]

Air Plan Revisions; California; Yolo-Solano Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to partially approve and partially disapprove a revision to the Yolo-Solano Air Quality Management District (YSAQMD) portion of the California State Implementation Plan (SIP). The revision concerns the YSAQMD's demonstration regarding reasonably available control technology (RACT) requirements for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or "standards") in the portion of the Sacramento Metropolitan nonattainment area under the jurisdiction of the YSAQMD.

DATES: This rule is effective July 31, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2018-0160. 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. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Eugene Chen, EPA Region IX, 75

Hawthorne St., San Francisco, CA 94105. By phone: (415) 947-4304 or by email at chen.eugene@epa.gov.

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

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Statutory and Executive Order Reviews

I. Proposed Action

On April 11, 2023 (88 FR 21572), the EPA proposed to partially approve and partially disapprove the California Air Resources Board's (CARB) submittal of the YSAQMD's RACT SIP for the 2008 Ozone National Ambient Air Quality Standards (NAAQS), as listed in Table 1 below.

TABLE 1—SUBMITTED DOCUMENT

Local agency	Document	Adopted	Submitted
YSAQMD	Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Analysis for the 2008 Federal Ozone Standard ("2017 RACT SIP").	09/13/2017	11/13/2017

We proposed to partially approve YSAQMD's 2017 RACT SIP because we determined that, except for the RACT elements for non-control technique guideline (CTG) major sources of nitrogen oxides (NO_x) and volatile organic compounds (VOC), it complied with the relevant Clean Air Act (CAA or "Act") requirements. We proposed to partially disapprove YSAQMD's 2017 RACT SIP because we identified two deficiencies that would preclude us from fully approving the submittal. First, we found that District Rule 2.38, "Standards for Municipal Solid Waste Landfills," which is relied upon to implement RACT for non-CTG major sources of VOC, has not been submitted for approval into the SIP, and therefore cannot be used to satisfy RACT requirements. Second, we found that District Rule 2.43, "Biomass Boilers," which the District relied upon to implement RACT for non-CTG major sources of NO_x, contains a provision that explicitly exempts affected units from complying with rule standards during periods of startup and shutdown and does not provide for an alternative emissions limitation during such periods. This provision is inconsistent with the EPA's Startup, Shutdown, and Malfunction (SSM) Policy as defined in

the EPA's 2015 SSM SIP Action.¹ The deficiencies are discussed in more detail in our proposed action.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period, which concluded on May 11, 2023 (April 11, 2023 (88 FR 21572)). We received one comment letter regarding our proposed action, from the YSAQMD and dated May 10, 2023. We have summarized substantive adverse comments included in this comment letter and provided our responses below. In addition to the substantive comments summarized below, the District's letter includes information about recent progress it has made to address deficiencies related to SSM exemptions identified in Rule 2.43, and comments regarding the EPA's communication to the District about the identified deficiencies leading up to publication of the proposed rulemaking.² The District's letter is included in the docket for this action.

¹ "State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown and Malfunction," 80 FR 33839 (June 12, 2015).

² The District's revisions to Rule 2.43 were submitted by CARB to the EPA on June 8, 2023 via the State Plan electronic Collection System (SPeCS).

Comment 1: The YSAQMD asserts that the District's 2017 RACT SIP identified the Recology Hay Road Landfill and the Yolo County Central Landfill as major sources of VOC in error. The District states that the VOC potential to emit (PTE) of each landfill is below the 25 tons per year (tpy) major source threshold for Severe nonattainment areas, and therefore not subject to VOC RACT requirements for major sources.

Response 1: On May 17, 2023, the EPA emailed the District with a request for further clarification and documentation demonstrating that the VOC PTE of each landfill was below major source thresholds.³ On May 19, 2023, the District replied with permitting information for each facility and indicated that, when excluding fugitive landfill emissions in accordance with EPA guidance, the VOC PTE of the Recology Hay Road Landfill and Yolo County Central Landfill is 13.04 tpy and 24.7 tpy respectively, which are below major source thresholds.⁴ Based on this additional documentation, and for the reasons discussed below, we agree with the District that the Recology Hay Road

³ Email dated May 17, 2023, from Eugene Chen (EPA) to Paul Hensleigh (YSAQMD), Subject: "RACT SIP Comment Letter follow up."

⁴ Email dated May 19, 2023, from Paul Hensleigh (YSAQMD) to Eugene Chen (EPA), Subject: "Re: RACT SIP Comment Letter follow up."

Landfill and Yolo County Central Landfill are not major sources of VOC, and are therefore not required to implement RACT for VOC.

The EPA defines fugitive emissions as “those emissions which could not reasonably pass through a stack, chimney, vent, or other functionally-equivalent opening.”⁵ A source’s fugitive emissions must be included when determining whether it qualifies as a major source if the source falls within one of 27 listed source

categories.⁶ Municipal solid waste landfills are not included in this list of source categories, and as a result are not required to include fugitive emissions toward major source applicability. Under additional EPA guidance related to landfills, if a landfill gas collection system is in operation, or if a landfill gas collection system could reasonably be designed to collect a landfill’s gas emissions, then those collected emissions are not fugitive and shall be considered in determining facility PTE.⁷

Both Recology Hay Road and Yolo County Central Landfill operate with active gas collection systems, and therefore only the portion of landfill gas that is not collected can be considered fugitive and excluded from consideration in determining VOC PTE.

The current title V operating permit (Permit No. F-01059-18, issued November 10, 2022) and statement of basis for the Recology Hay Road Landfill lists the following emission units and corresponding VOC PTE:⁸

TABLE 1—RECOLOGY HAY ROAD LANDFILL VOC PTE

Unit ID	Equipment description	VOC PTE (tpy)
P-13-16	124-horsepower (hp) Caterpillar IC engine (Certified Tier IV engine)	0.01
P-14-16(a)	124-hp Caterpillar IC engine (Certified Tier IV engine)	0.01
P-28-98(a)	One (1) 500-gallon aboveground gasoline storage tank, one gasoline dispenser (1 nozzle), and one gasoline pressure/vacuum vent valve.	0.04
P-51-17	Various equipment including two (2) portable crushers, two (2) portable screens, and two (2) stackers, powered by Off-road engines that also provide propulsion.	0.01
P-64-00	Petroleum contaminated soil handling for daily and intermediate cover material	13.00
P-81-10	7-acre lined containment pond and drying areas	0.01
P-85-06(a8)	Municipal Solid Waste landfill not to exceed a total maximum design capacity of 35.6 million cubic yards (17.0 million megagrams).	24.62
P-59-21	174-hp Caterpillar Engine (Certified Tier IV engine)	0.01
	Total	37.66
	Total (excluding Unit ID P-85-06(a8))	13.04

The YSAQMD asserts that the municipal solid waste landfill’s 24.62 tpy VOC PTE (Unit ID P-85-06(a8)) consists of landfill fugitive emissions. Excluding these emissions from consideration towards major source applicability would result in a facility-wide VOC PTE of 13.04 tpy. Based upon a review of permitting information, we note that while Unit ID P-86-06(a8) includes fugitive VOC emissions from the landfill, it also includes VOC emissions from the flaring of landfill gas

captured by the collection system.⁹ We do not consider it appropriate for VOC emissions from flaring activities to be considered fugitive since they represent the destruction of collected landfill gas. The title V permit and statement of basis do not identify the portion of VOC PTE attributable only to flaring activities, but based on the physical design and enforceable emission limits applicable to flaring activities, we estimate the VOC PTE to be 3.67 tpy.¹⁰ Including this 3.67 tpy VOC PTE results in a facility

wide VOC PTE of 16.71 tpy, which is below the Severe nonattainment area major source threshold of 25 tpy. As a result, we agree that the Recology Hay Road Landfill is not a major source of VOC, and is not required to implement RACT for VOC.

The current title V operating permit (Permit No. F-01392-8, issued March 13, 2018) and statement of basis for the Yolo County Central Landfill lists the following emission units and corresponding VOC PTE:¹¹

TABLE 2—YOLO COUNTY CENTRAL LANDFILL VOC PTE

Unit ID	Equipment description	VOC PTE (tpy)
P-15-05(a)	Landfill not to exceed max design capacity of 49 million cubic yards	51.03
P-25-07	317-hp emergency engine (Certified Tier III engine)	0.01
P-31-10	Various equipment for dewatering and aeration of non hazardous liquid waste with odor potential (NHLWOP)	0.01
P-71-06(t)	157-hp emergency engine (Certified Tier II engine)	0.01
P-49-14	Receiving Storage and use of NHLWOP	0.93
P-90-18	In Vessel Digester Operation	2.73
P-26-98(t2)	Negative pressure landfill gas collection system, landfill gas flare	4.11
P-78-98(t)	Engine 1A, 805-hp landfill gas IC engine	4.11
P-79-98(t)	Engine 2, 805-hp landfill gas IC engine	4.11

⁵ 40 CFR 70.1; 70.2 (title V definitions). This definition also applies under the NSR program. See 40 CFR 51.165(a)(1)(ix).

⁶ 40 CFR 70.2; 40 CFR 51.165(a)(1)(iv)(C).

⁷ Memorandum dated October 21, 1994, from John S. Seitz, Director, Office of Air Quality Planning and Standards, U.S. EPA, to EPA Regional Air Directors, Regions I–X, Subject: “Classification

of Emissions from Landfills for NSR Applicability Purposes.”

⁸ See Permit No. F-01059-18, Recology Hay Road Landfill title V permit, Permit No. F-01059-18, Statement of Basis, and Permit to Operate, Unit ID P-86-06(a8).

⁹ Id.

¹⁰ Based upon a flare VOC permit limit of 14.1 ppm (@3% O₂) and maximum flare heat rate of 45.6 MMBtu/hr.

¹¹ See Permit F-01392-8, Yolo County Central Landfill title V permit, Permit No. F-01392-8, Statement of Basis, and Emission Evaluation C-07-164.

TABLE 2—YOLO COUNTY CENTRAL LANDFILL VOC PTE—Continued

Unit ID	Equipment description	VOC PTE (tpy)
P-80-98(t)	Engine 3, 805-hp landfill gas IC engine	4.25
P-81-98(t)	Engine 4A, 805-hp landfill gas IC engine	4.22
P-87-98(t)	Engine 5A, 805-hp landfill gas IC engine	4.22
P-28-17	Concrete crushing plant	
P-29-17	Screening of waste and wood debris	
P-30-17	Grinding and shredding of waste and wood debris	0.09
	Total	75.7
	Total (excluding Unit P-15-05(a))	24.7

The District asserts that the municipal solid waste landfill's 51.03 tpy VOC PTE (Unit ID P-15-05(a)) consists of landfill fugitive emissions. Excluding these emissions from consideration towards major source applicability would result in a facility-wide VOC PTE of 24.7 tpy. Based upon a review of permitting information, we agree that the 51.03 VOC PTE attributable to P-15-05(a) are fugitive landfill emissions, and note that the gas collection system and landfill flare are accounted for separately as Unit ID P-26-98(t2). With regard to the other permitted emission units, and in particular the landfill gas engines that comprise the majority of the non-fugitive VOC PTE, we note that the facility's title V permit establishes several emission and operating limits on a per-engine basis, including annual VOC tpy limits, VOC concentration limits expressed in parts per million (ppm), and landfill gas fuel usage limitations expressed in million standard cubic feet per year (MMCF/yr). The title V permit also contains requirements for annual source testing, recordkeeping of fuel usage and operating hours, and reporting requirements to ensure the practical enforceability of emission and operating limits. In addition, the title V permit establishes a landfill flare VOC emission limit and landfill gas fuel usage limit for Unit ID P-26-98(t2), and also requires an annual source test, recordkeeping of landfill gas fuel usage, and for the flare to be operated within the parameter ranges established during the most recent source test. We consider these monitoring, reporting, and recordkeeping requirements to ensure the practical enforceability of emission limits for the landfill flare. Based upon this information, we agree with the District that the VOC PTE of the Yolo County Central Landfill is 24.7 tpy, which is below the Severe nonattainment area major source

threshold of 25 tpy.¹² As a result, we agree that the Yolo County Central Landfill is not a major source of VOC, and is not required to implement RACT for VOC. For this reason, as described below, we are issuing a final approval of the RACT element for non-CTG major sources of VOC.

Comment 2: The YSAQMD asserts that even if the landfills subject to its regulatory authority were major sources of VOC, they are subject to federally enforceable requirements that implement RACT through a combination of California's statewide landfill methane regulation (LMR) and an EPA Federal implementation plan (FIP). The District notes that the 2017 RACT SIP identifies landfill requirements as federally enforceable through California's CAA section 111(d) State Plan approved by the EPA on September 23, 1999. The District asserts that California later adopted and submitted its statewide LMR for SIP approval and that the EPA proposed to partially approve the LMR in 2020, and in May 2021 proposed a FIP in 40 CFR part 62 subpart OOO to cover identified deficiencies in the LMR.

Response 2: As discussed in our response to the previous comment, we agree with the District that the Recology Hay Road Landfill and Yolo County Central Landfill are not major sources of

VOC, and are therefore not required to implement RACT for VOC. As a result, we do not consider it necessary to address issues regarding implementation of RACT at these sources. However, we wish to clarify that the EPA's approval of a performance standards plan under CAA section 111(d) is different from approval of a SIP submittal under CAA section 110. Thus, while we have issued both a final partial approval/partial disapproval of the California LMR¹³ and a final rule promulgating a partial Federal plan for municipal solid waste landfills under CAA section 111(d),¹⁴ we have not approved these landfill rules as a SIP revision under CAA section 110(k) or issued a FIP under CAA section 110(c), and we are unaware of any pending state submittal of the LMR or District landfill VOC RACT rules for SIP approval. The EPA's SIP approval of RACT-level control rules for landfills regulated by the District would ensure that any future major source landfills in the area meet RACT requirements. We invite the District or CARB to discuss this option further with the EPA.

III. EPA Action

As discussed in Section II of this preamble above, we received a public comment from the YSAQMD providing additional information relevant to our proposed disapproval of the RACT element for non-CTG major sources of VOC. The basis for our proposed disapproval was the lack of enforceable SIP requirements implementing VOC RACT for two municipal solid waste landfills that the 2017 RACT SIP identified as non-CTG major sources of VOC. Based upon the District's comment letter and additional information, we no longer consider these two municipal solid waste landfills to be major VOC sources, and therefore find that these sources are not

¹² The 24.7 tpy VOC PTE relies on conservative assumptions regarding landfill gas usage and accordingly represents an overestimate of the facility's potential VOC emissions. For example, the aggregated landfill gas usage limits for the flare and engines (1.154 MMCF/yr) is greater than the total amount of landfill gas that is permitted to be collected from the landfill (997.1 MMCF/yr), per title V Permit No. F-01392-8, Conditions B.69 through B.80. Since the sum of destroyed landfill gas cannot exceed the total amount of collected landfill gas, the facility VOC PTE reflects a certain amount of double-counting. The amount of double-counting would be difficult to quantify precisely given the variety of landfill gas destruction scenarios, but as an example, if the entirety of the collected landfill gas were destroyed by the engines and not by the landfill flare, then the landfill flare VOC PTE of 2.73 tpy would represent an additional margin between facility PTE and the major source threshold.

¹³ 85 FR 1121 (January 8, 2020).

¹⁴ 86 FR 27756 (May 21, 2021).

required to implement VOC RACT. As a result, the only District rule relied upon to implement RACT for non-CTG major sources of VOC is Rule 2.41, "Expandable Polystyrene Manufacturing Operations," which implements limits

VOC emissions from manufacture of expandable polystyrene products. As discussed in our April 11, 2023 (88 FR 21572) proposed action, Rule 2.41 implements RACT. We are therefore issuing a final approval of the RACT

element for non-CTG major sources of VOC. This represents the only change from our proposed action, as summarized in Table 3 of this preamble below.

TABLE 3—LIST OF RACT ELEMENTS—2008 OZONE NAAQS

CTG document No.	RACT element	District rule implementing RACT	Negative declaration submitted	EPA proposed action	EPA final action
EPA-450/R-75-102 ...	Design Criteria for Stage I Vapor Control—Gasoline Service Stations.	2.22 (Gasoline Dispensing Facilities)		Approval	Approval.
EPA-450/2-77-008	Surface Coating of Cans		Yes	None ^a	None. ^a
EPA-450/2-77-008	Surface Coating of Coils		Yes	None ^a	None. ^a
EPA-450/2-77-008	Surface Coating of Paper		Yes	None ^a	None. ^a
EPA-450/2-77-008	Surface Coating of Fabric		Yes	None ^a	None. ^a
EPA-450/2-77-008	Surface Coating of Automobiles and Light-Duty Trucks.		Yes	None ^a	None. ^a
EPA-450/2-77-022	Solvent Metal Cleaning	2.31 (Solvent Cleaning and Degreasing).		Approval	Approval.
EPA-450/2-77-025	Refinery Vacuum Producing Systems, Waste-water Separators, and Process Unit Turn-arounds.		Yes	None ^a	None. ^a
EPA-450/2-77-026	Tank Truck Gasoline Loading Terminals	2.21 (Organic Liquid Storage and Transfer).		Approval	Approval.
EPA-450/2-77-032	Surface Coating of Metal Furniture		Yes	None ^a	None. ^a
EPA-450/2-77-033	Surface Coating of Insulation of Magnet Wire		Yes	None ^a	None. ^a
EPA-450/2-77-034	Surface Coating of Large Appliances		Yes	None ^a	None. ^a
EPA-450/2-77-035	Bulk Gasoline Plants	2.21 (Organic Liquid Storage and Transfer).		Approval	Approval.
EPA-450/2-77-036	Storage of Petroleum Liquids in Fixed-Roof Tanks.		Yes	None ^a	None. ^a
EPA-450/2-77-037	Cutback Asphalt	2.28 (Cutback and Emulsified Asphalts).		Approval	Approval.
EPA-450/2-78-015	Surface Coating of Miscellaneous Metal Parts and Products.	2.25 (Metal Parts and Products Coating Operations).		Approval	Approval.
EPA-450/2-78-029	Manufacture of Synthesized Pharmaceutical Products.		Yes	None ^a	None. ^a
EPA-450/2-78-030	Manufacture of Pneumatic Rubber Tires		Yes	None ^a	None. ^a
EPA-450/2-78-032	Factory Surface Coating of Flat Wood Paneling ..		Yes	None ^a	None. ^a
EPA-450/2-78-033	Graphic Arts-Rotogravure and Flexography		Yes	None ^a	None. ^a
EPA-450/2-78-036	Leaks from Petroleum Refinery Equipment		Yes	None ^a	None. ^a
EPA-450/2-78-047	Petroleum Liquid Storage in External Floating Roof Tanks.	2.21 (Organic Liquid Storage and Transfer).		Approval	Approval.
EPA-450/2-78-051	Leaks from Gasoline Tank Trucks and Vapor Collection Systems.	2.21 (Organic Liquid Storage and Transfer).		Approval	Approval.
EPA-450/3-82-009	Large Petroleum Dry Cleaners		Yes	None ^a	None. ^a
EPA-450/3-83-006	Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.		Yes	None ^a	None. ^a
EPA-450/3-83-007	Leaks from Natural Gas/Gasoline Processing Plants.		Yes	None ^a	None. ^a
EPA-450/3-83-008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.		Yes	None ^a	None. ^a
EPA-450/3-84-015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.		Yes	None ^a	None. ^a
EPA-450/4-91-031	Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.		Yes	None ^a	None. ^a
EPA-453/R-96-007 ...	Wood Furniture Manufacturing Operations		Yes	None ^a	None. ^a
EPA-453/R-94-032, 61 FR 44050; 8/27/96.	ACT Surface Coating at Shipbuilding and Ship Repair Facilities Shipbuilding and Ship Repair Operations (Surface Coating).		Yes	None ^a	None. ^a
EPA-453/R-97-004, 59 FR 29216; 6/06/94.	Aerospace MACT and Aerospace (CTG & MACT)		Yes	None ^a	None. ^a
EPA-453/R-06-001 ...	Industrial Cleaning Solvents	2.31 (Solvent Cleaning and Degreasing).		Approval	Approval.
EPA-453/R-06-002 ...	Offset Lithographic Printing and Letterpress Printing.	2.29 (Graphic Arts Printing Operations).		Approval	Approval.
EPA-453/R-06-003 ...	Flexible Package Printing		Yes	None ^a	None. ^a
EPA-453/R-06-004 ...	Flat Wood Paneling Coatings		Yes	None ^a	None. ^a
EPA 453/R-07-003	Paper, Film, and Foil Coatings		Yes	None ^a	None. ^a
EPA 453/R-07-004	Large Appliance Coatings		Yes	None ^a	None. ^a
EPA 453/R-07-005	Metal Furniture Coatings		Yes	None ^a	None. ^a
EPA 453/R-08-003	Miscellaneous Metal Parts Coatings, Table 2—Metal Parts and Products.	2.25 (Metal Parts and Products Coating Operations).		Approval	Approval.
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings, Table 3—Plastic Parts and Products.		Yes	None ^a	None. ^a
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings, Table 4—Automotive/Transportation and Business Machine Plastic Parts.		Yes	None ^a	None. ^a

TABLE 3—LIST OF RACT ELEMENTS—2008 OZONE NAAQS—Continued

CTG document No.	RACT element	District rule implementing RACT	Negative declaration submitted	EPA proposed action	EPA final action
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings, Table 5—Pleasure Craft Surface Coating.		Yes	None ^a	None. ^a
EPA 453/R-08-003	Miscellaneous Plastic Parts Coatings, Table 6—Motor Vehicle Materials.		Yes	None ^a	None. ^a
EPA 453/R-08-004	Fiberglass Boat Manufacturing Materials	2.30 (Polyester Resin Operations)		Approval	Approval.
EPA 453/R-08-005	Miscellaneous Industrial Adhesives	2.33 (Adhesive Operations)		Approval	Approval.
EPA 453/R-08-006	Automobile and Light-Duty Truck Assembly Coatings.		Yes	None ^a	None. ^a
	Non-CTG Major Sources of NO _x	2.27 (Large Boilers)		Disapproval ^b	Disapproval. ^b
		2.32 (Stationary Internal Combustion Engines).			
		2.43 (Biomass Boilers)			
	Non-CTG Major Sources of VOC	2.41 (Expandable Polystyrene Manufacturing Operations).		Disapproval ^c	Approval. ^d

^aPreviously approved on April 5, 2018 (83 FR 14754).

^bAs described in greater detail in the Technical Support Document (TSD), the proposed disapproval for the non-CTG major sources of NO_x element is based in the deficiencies noted in Rule 2.43 (Biomass Boilers).

^cAs described in greater detail in our TSD, the proposed disapproval for the non-CTG major sources of VOC element is based on the deficiencies noted in Rule 2.38 (Standards for Municipal Solid Waste Landfills).

^dAs described in greater detail in Section II of this preamble, our final action approving the non-CTG major sources of VOC element is based upon the fact that Rule 2.41 implements RACT, and that Rule 2.38 is no longer relied upon to implement RACT.

As authorized in section 110(k)(3) of the Act, the EPA is partially disapproving the 2017 RACT SIP with respect to the RACT element for non-CTG major sources of NO_x, and partially approving the remainder of the 2017 RACT SIP.

IV. 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. 740(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to review state choices, and approve those choices if they meet the minimum criteria of the Act. Accordingly, this final action partially approves and partially disapproves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law.

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

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

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

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

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

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law.

Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it merely partially approves and partially disapproves state law as meeting Federal requirements. Furthermore, the EPA's Policy on Children's Health does not apply to this action.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

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

The District did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goals of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

K. Congressional Review Act (CRA)

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

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 29, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and

shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

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

Dated: June 22, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations 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 F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(505)(ii)(A)(2) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

- (c) * * *
- (505) * * *
- (ii) * * *
- (A) * * *

(2) Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) for the 2008 8-Hour Ozone National Ambient Air Quality Standards (NAAQS) (“Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Analysis”), as adopted on September 13, 2017, except the RACT determination for non-CTG major sources of NO_x.

* * * * *

■ 3. Section 52.237 is amended by adding paragraph (b)(6)(ii) to read as follows:

§ 52.237 Part D disapproval.

* * * * *

- (b) * * *
- (6) * * *

(ii) RACT determination for non-CTG major sources of Nitrogen Oxides (NO_x) for the 2008 ozone NAAQS, as contained in the submittal titled “Reasonably Available Control

Technology (RACT) State Implementation Plan (SIP) Analysis for the 2008 Federal Ozone Standard,” as adopted on September 13, 2017, and submitted on November 13, 2017.

* * * * *

[FR Doc. 2023–13754 Filed 6–29–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0338; FRL–10269–02–R9]

Approval, Limited Approval and Limited Disapproval of California Air Plan Revisions; Mojave Desert Air Quality Management District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing an approval and a limited approval and limited disapproval of revisions to the Mojave Desert Air Quality Management District (MDAQMD or “District”) portion of the California State Implementation Plan (SIP). These revisions concern the District’s New Source Review (NSR) permitting program for new and modified sources of air pollution under part D of title I of the Clean Air Act (CAA or “Act”). This action updates the District’s portion of the California SIP with ten revised rules. Under the authority of the CAA, this action simultaneously approves local rules that regulate emission sources and directs the District to correct rule deficiencies.

DATES: This rule is effective July 31, 2023.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2022–0338. 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. If

you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: La Weeda Ward, Permits Office (Air-3-1), U.S. Environmental Protection Agency, Region IX, (213) 244-1812, ward.laweeda@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us,” and “our” refer to the EPA.

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Proposed Action

On November 25, 2022 (87 FR 72434), the EPA proposed approval of five rules and a limited approval and limited disapproval of five rules that were submitted for incorporation into the California SIP. Table 1 shows the rules in the California SIP that will be removed or superseded by this action, while Table 2 shows the rules that the State submitted for inclusion in the California SIP.¹

TABLE 1—RULES TO BE REMOVED OR SUPERSEDED

Rule No.	Rule title	Adoption date	Submittal date	EPA action date	Federal Register citation
206—San Bernardino County.	Posting of Permit to Operate	^a 02/01/1977	06/06/1977	11/09/1978	43 FR 52237
206—Riverside County	Posting of Permit to Operate	02/06/1976	04/21/1976	11/09/1978	43 FR 52237
219—San Bernadino County.	Equipment Not Requiring a Permit	^a 02/01/1977	6/6/1977	11/9/1978	43 FR 52237
219—Riverside County	Equipment Not Requiring a Written Permit Pursuant to Regulation II.	09/04/1981	10/23/1981	07/06/1982	47 FR 29231
1300	General	03/25/1996	7/23/1996	11/13/1996	61 FR 58133
1301	Definitions	03/25/1996	7/23/1996	11/13/1996	61 FR 58133
1302	Procedure	03/25/1996	7/23/1996	11/13/1996	61 FR 58133
1303	Requirements	03/25/1996	7/23/1996	11/13/1996	61 FR 58133
1304	Emissions Calculations	03/25/1996	7/23/1996	11/13/1996	61 FR 58133
1305	Emission Offsets	03/25/1996	7/23/1996	11/13/1996	61 FR 58133
1306	Electric Energy Generating Facilities	03/25/1996	7/23/1996	11/13/1996	61 FR 58133
1402	Emission Reduction Credit Registry	06/28/1995	8/10/1995	01/22/1997	62 FR 3215

^a These rules were adopted by California Air Resources Board (CARB) Ex. Ord. G-73 on 2/1/1977 and substituted into the 6/6/1977 submittal to the EPA after the original adoption date of 1/9/1976 because the two versions were identical, and the earlier version was submitted on behalf of the Southern California Air Pollution Control District (SoCalAPCD) (42 FR 1273).

TABLE 2—SUBMITTED RULES

Rule No.	Rule title	Amended date	Submitted date ^a
206	Posting of Permit to Operate	02/22/2021	10/15/2021
219	Equipment Not Requiring a Permit	01/25/2021	07/23/2021
1300	New Source Review General	03/22/2021	07/23/2021
1301	New Source Review Definitions	03/22/2021	07/23/2021
1302 ^b	New Source Review Procedure	03/22/2021	07/23/2021
1303	New Source Review Requirements	03/22/2021	07/23/2021
1304	New Source Review Emissions Calculations	03/22/2021	07/23/2021
1305	New Source Review Emission Offsets	03/22/2021	07/23/2021
1306	New Source Review for Electric Energy Generating Facilities	03/22/2021	07/23/2021
1402	Emission Reduction Credit Registry	05/19/1997	08/05/1997

^a The submittal for Rules 219, 1300, 1301, 1302, 1303, 1304, 1305, and 1306 was transmitted to the EPA via a letter from CARB dated July 22, 2021, and received by the EPA on July 23, 2021. Rule 206 was transmitted electronically on October 15, 2021, as an attachment to a letter dated October 14, 2021. Rule 1402 was submitted on August 1, 1997, and received by the EPA on August 5, 1997.

^b As we stated in section 5.9.1 of our technical support document (TSD), the State did not submit for inclusion in the SIP subsections (C)(5) and (C)(7)(c) of Rule 1302.

In our proposal, we proposed approval of Rules 206, 219, 1300, 1306, and 1402 as authorized under section 110(k)(3) of the Act. As authorized in sections 110(k)(3) and 301(a) of the

Act,² we proposed a limited approval and limited disapproval of Rules 1301, 1302, 1303, 1304, and 1305 because although they fulfill most of the relevant CAA requirements and strengthen the

SIP, they also contain six deficiencies, summarized below, that do not fully satisfy the relevant requirements for preconstruction review and permitting under section 110 and part D of the Act:

¹ In the incorporation by reference (IBR) section of our proposed action (87 FR 72434) inadvertently refers to Table 1 as opposed to Table 2 for the list of submitted rules that are intended to replace the rules in the SIP. However, we explain in Section C of our proposed rulemaking that “the rules listed in Table 2 are intended to replace the SIP-approved

rules listed in Table 1.” We also state in Section F of our proposed rulemaking that, “[i]f finalized, this action would incorporate into the SIP the submitted rules listed in Table 2 for which we have proposed approval or limited approval/limited disapproval”

² If a portion of a plan revision meets all the applicable CAA requirements, CAA sections 110(k)(3) and 301(a) authorize the EPA to approve the plan revision in part and disapprove the plan revision in part.

1. The use of the term “contract” in the District’s rules as interchangeable with the term “permit” is a deficiency because, as used in the specific contexts we identified in our proposed action, the term “contract” is not an acceptable alternative to the term “permit.”

2. The calculation procedures used in the District’s rules to determine the amount of offsets required in certain situations do not comply with CAA section 173(c)(1) or 40 CFR 51.165(a)(3)(ii)(J) or (a)(1)(vi)(E). Rule 1304 uses a potential-to-potential test for calculating the quantity of “simultaneous emission reductions” (SERs) that can be used as offsets for a “Modified Major Facility.” Pursuant to Rule 1304(C)(2)(d), SERs at a Modified Major Facility are calculated using the potential to emit (PTE) in place of Historic Actual Emissions (HAE). Calculating emissions decreases using potential emissions as the baseline allows reductions “on paper” that do not represent real emissions reductions. The deficiency in Rule 1304, through cross-references, also causes related deficiencies in Rules 1301, 1302, 1303, and 1305.

3. The definitions for “Major Modification” and “Modification (Modified)” pursuant to Rule 1301(NN) and 1301(JJ), respectively, are deficient because they do not conform with Federal requirements. The definition of “Modification (Modified)” excludes modifications that do not result in a “Net Emissions Increase,” which is defined in Rule 1301(QQ) as: “An emission change as calculated pursuant to District Rule 1304(B)(2) which exceeds zero.” If there is no net emissions increase, as defined in Rule 1301(QQ) and Rule 1304(B)(2), a permit applicant can avoid NSR requirements entirely (*i.e.*, best available control technology (BACT), offsets, visibility, etc.) because it can effectively exclude the proposed project from being considered a “Modification” and hence a “Major Modification,” using calculation procedures that do not conform to the Federal definition for Major Modification pursuant to 40 CFR 51.165(a)(1)(v)(A)(1); the calculation procedures for determining offsets pursuant to 40 CFR 51.165(a)(3)(ii)(J); and the criteria for determining the emission decreases that are creditable pursuant to 40 CFR 51.165(a)(1)(vi)(E)(1).

4. The District’s use of the term “proceed” in Rule 1304 is a deficiency because the word “precede” (or a synonym of “precede”) should be used.

5. The provision in Rule 1305 allowing for interprecursor trading (IPT)

for ozone precursors is a deficiency because IPT is no longer permissible.

6. The District rules do not contain the de minimis plan requirements contained in CAA section 182(c)(6) that apply to areas classified as Severe nonattainment.³

As discussed in our proposal, this action is consistent with CAA sections 110(l) and 193. It will not relax any existing SIP provision, and it will not interfere with applicable attainment and reasonable further progress requirements or other applicable CAA requirements. This action will not relax any pre-November 15, 1990 requirements in the SIP, and therefore changes to the SIP resulting from this action will ensure greater or equivalent emissions reductions of ozone and its precursors and PM₁₀ and its precursors in the District.

Finally, we proposed to approve, under 40 CFR 51.307, the District’s visibility provisions for sources subject to the District’s nonattainment new source review (NNSR) requirements. Accordingly, we also proposed to revise 40 CFR 52.281(d) to add the District to the list of areas not subject to the visibility Federal Implementation Plan (FIP) at 40 CFR 52.28, to clarify that the FIP does not apply to the District.

The EPA’s proposal and technical support document (TSD) for this action have more information and analysis on the District’s submittal, the deficiencies, and our proposed approvals.

II. Public Comments and EPA Responses

The public comment period on the proposed rule opened on November 25, 2022, the date of its publication in the **Federal Register**, and closed on December 27, 2022. During this period, the EPA received one comment letter submitted by the Mojave Desert Air Quality Management District (MDAQMD or the “District”). A copy of the District’s comment letter is included in the docket for this action and is accessible at www.regulations.gov. In this section, we provide a summary of and response to the MDAQMD’s comments.

Comment #1: The District states that portions of the EPA’s proposed action are inopportune. The District states that the EPA did not communicate with its staff on any substantive issues during its evaluation of CARB’s submittal of the District’s revisions to its NSR program despite previously working with its staff

to address identified deficiencies from a prior submittal. The District states that the only communication it received from the EPA after adopting rule revisions were requests for copies of various SIP rules and accompanying information, most of which the District had previously provided to the EPA in the rule development process. The District states that the EPA could have communicated trivial deficiencies to the District prior to publishing the proposed action, which would have allowed the District to provide commitments to amend its rules and that such a process would have allowed issues to be narrowed to those that truly require interpretation or judicial review.

Response to Comment #1: The EPA does not read this comment as asserting that our proposed action on the submitted rules was legally or technically deficient; rather, we understand the comment to express dissatisfaction with the EPA’s communication after CARB’s submittal of the revised rules on July 23, 2021.

The EPA values its relationships with state, local, and tribal air agencies and strives to maintain open and transparent communications with them. Prior to our receipt of the District’s submittal, the EPA, the District, and CARB committed significant resources to meeting, on a bi-weekly basis from approximately March 2020 to June 2021, for detailed discussions of the NSR program deficiencies we identified in a letter to the District dated December 19, 2019.⁴ After the conclusion of this process, and following CARB’s submission of the District’s revised rules, the EPA identified a few additional issues not identified in our December 19, 2019 letter. EPA staff are available to continue to work with the District to address questions and concerns with revisions necessary to correct the deficiencies, with the goal of full approval of revisions to the District’s

⁴ 87 FR 72434 (November 25, 2022). Technical Support Document, page 11. The December 19, 2019 letter, from Lisa Beckham to Brad Poiriez, which the District mentions in footnote 17 of its comment letter, follows our October 10, 2019 letter from Gerardo Rios, Manager, Air Permits Office, EPA Region IX, to Brad Poiriez, Air Pollution Control Officer, MDAQMD, in which we provided feedback in response to the MDAQMD’s invitation to review and comment on the District’s proposed adoption of its “70 ppb Ozone Standard Implementation Evaluation: RACT SIP Analysis; Federal Negative Declarations; Certification of Nonattainment New Source Review Program; and, Emission Statement Certification (70 ppb O₃ Evaluation).” In the October 10, 2019 letter, we stated that we would send a comprehensive list of issues to “provide the District sufficient time to adopt the necessary rule revisions and make a new NSR submittal to meet the implementation requirements of the 2015 ozone NAAQS [national ambient air quality standards].”

³ CAA Section 182(d), which was added by the Clean Air Act Amendments of 1990, details plan submission requirements for Severe non-attainment areas and includes all the provisions under section 182(c) for Serious non-attainment areas.

rules and a fully approved NSR program.

In addition, we understand the District's reference to "commitments" to suggest that the EPA could have proposed a conditional approval under CAA section 110(k)(4) rather than proposing a limited approval and limited disapproval. As authorized under CAA sections 110(k)(3) and 301(a), we are taking action to finalize a limited approval and limited disapproval of the submitted rules that contain the deficient provisions we identified in our proposed action.

Comment #2: The District states that the EPA's proposed rulemaking does not fully identify its existing NSR program. The District states that Table 1 in the proposed action and Table 2 in the accompanying Technical Support Document (TSD) are incomplete because they fail to mention SIP-approved Rules 201, "Permit to Construct," 202, "Temporary Permit to Operate," 203, "Permit to Operate," and 204, "Permit Conditions." The District points out that Rules 201, 202, 203, and 204 are currently in the SIP, but states that they should have been listed in the proposed action because they are important for understanding portions of the District's NSR program. The District then requests that the EPA officially acknowledge that Rules 201, 202, 203, and 204 are part of District's NSR Program.

Response to Comment #2: The EPA acknowledges that SIP-approved Rules 201, 202, 203, and 204 are part of the District's SIP-approved NSR program and clarifies that the purpose of Table 1 in our proposed action and Table 2 in the TSD is to present the submitted rules and the current SIP-approved versions of the submitted rules.

Comment #3: The District states that the EPA's proposed rulemaking identifies deficiencies that are present in the current SIP-approved rules and does not explain why these previously approved provisions are no longer approvable. The District states that it would appreciate a more detailed explanation of the underlying provisions of the CAA that have changed to make the previously approved SIP provisions, which were adequate for SIP approval in 1996, not approvable now. The District states that it is not aware of any amendments to the CAA since 1990, therefore it requests an updated, specific analysis with appropriate citations, documentation, and rationale for the changes to EPA's interpretations that render previously approved NSR program provisions not approvable. The District states that it would appreciate a more detailed analysis—not mere citations of current

regulations—regarding the specific changes in the EPA regulations and policy that now render previously approved provisions deficient. The District states that the TSD associated with the EPA's proposed action does not provide a sufficient explanation of the EPA's interpretation of the CAA requirements.

Response to Comment #3: We disagree with the District's comment that our proposed action does not provide sufficient explanation or analysis of the deficiencies identified. The EPA provided its rationale as to why the submitted revisions to the SIP-approved rules, while deficient, represent an overall strengthening of the SIP.⁵ Our proposed action and the TSD cite to specific provisions in the CAA and its implementing regulations in 40 CFR part 51 that form the basis for the EPA's disapproval of specific provisions in the District's revised NSR rules.

As the District notes, the EPA last approved the District's Regulation XIII into the SIP in 1996. In 2002, the EPA revised its NSR regulations at 40 CFR 51.165.⁶ These revisions included the addition of 40 CFR 51.165(a)(3)(ii)(J). As we discuss in this document and in our proposed action and accompanying TSD, the District's submitted rules are inconsistent with the requirements in 40 CFR 51.165(a)(3)(ii)(J) and are therefore deficient.⁷ In particular, our proposed action explains that 40 CFR 51.165(a)(3)(ii)(J) requires offsets for each major modification at a major source based on the difference between pre-modification actual emissions and post-modification PTE.⁸ Our responses to Comments 5 and 6 below provide additional explanation of this issue. The EPA's interpretation of this provision is reasonable and is consistent with our actions regarding other submittals of NSR rules for SIP approval.⁹

⁵ See 87 FR 72436–38; TSD Sections 5–10.

⁶ 67 FR 80185 (December 31, 2002).

⁷ We explained in our TSD that the calculation of the offset quantity to use an actual emissions baseline is applicable to offsets that are being used to allow construction of new major sources or major modifications. The District can offset its minor sources and minor modifications differently than the required methods specified for major sources and major modifications.

⁸ See, e.g., "Response 4," 81 FR 50339, 50340 (August 1, 2016).

⁹ See, e.g., 81 FR 50339 (August 1, 2016), in which we finalized a limited approval/limited disapproval action on the Bay Area Air Quality Management District's NSR program. The Bay Area Air Quality Management District subsequently revised and resubmitted its rules, which the EPA approved in the rulemaking titled: "Revisions to California State Implementation Plan; Bay Area Air Quality Management District; Stationary Sources; New Source Review," 83 FR 8822 (March 1, 2018). See also "Revision of Air Quality Implementation Plan; California; Sacramento Metropolitan Air

Comment #4a (Inaccuracies regarding Rule 219): The District states that the EPA's TSD contains inaccuracies and misstatements regarding MDAQMD Rule 219. The District states that the EPA's statement in the TSD that Rule 219 exempts certain emission units from NSR is "manifestly untrue." The District describes its permitting program as emissions unit-based, and distinguishes it from the Federal regulatory scheme, which the District describes as facility-based. The District states that the "net result" is that while a specific emissions unit may be exempt from permitting requirements, it "will still undergo the NSR process." The District cites Rules 1301 and 1304 to support its position that its NSR program requires emissions changes to be determined both on an emissions unit by emissions unit basis and in regard to the facility as a whole, and it cites to Rule 219(B)(4) to support its position that Rule 219 requires emissions from exempt equipment to be included in NSR calculations. The District further states that while Rule 219 exempts certain emissions units from obtaining "paper" permits, it does not exempt emissions units or an entire facility containing such units from other District requirements, such as specific emissions limits and monitoring, recordkeeping, and source testing requirements, as well as the requirement to undergo at least a portion of the NSR analysis as set forth in Rule 1302, among others.

The District states that "USEPA has expressed concerns in the past" that a facility could escape NSR review if it were composed entirely of exempt equipment and explains that there are several backstops that prevent facilities that consist solely of equipment that is potentially exempt under Rule 219 from escaping review, such as actions undertaken by enforcement personnel and local land use agencies pursuant to state law. The District requests that the notation regarding the nature and effect of Rule 219 as part of its NSR program be corrected or clarified in the EPA's TSD.

Response to Comment #4a (Inaccuracies regarding Rule 219): The EPA proposed to fully approve Rule 219 as amended on January 25, 2021, because we have determined that it satisfies all relevant CAA requirements. We do not interpret the District's comment as an assertion that our proposed action to fully approve Rule 219 is incorrect; rather, the EPA understands the District's comment to take issue with a statement in section

Quality Management District; Stationary Source Permits," 78 FR 53270 (August 29, 2013).

5.7 of our TSD, specifically, that Rule 219 “is a rule that specifies which sources are exempt from the New Source Review program for regulated NSR pollutants.”¹⁰ We agree that this statement warrants clarification that we determined the District’s NSR program requires a facility-level review of emissions from a proposed project, including emissions from equipment otherwise exempt from permitting requirements, and that Rule 219 is consistent with 40 CFR 51.160(e), which allows states to exclude some sources from NSR requirements (*i.e.*, lowest achievable emission rate (LAER) and offsets), as well as public notice, by not requiring those sources to obtain a permit. There is a distinction between sources subject to NSR requirements and sources that are simply part of the District’s NSR program. Even emissions from equipment that is exempt from permitting requirements must be included when making a major source determination. Rules 201 and 203 require that essentially all sources must obtain an authority to construct and a permit to operate, but Rule 219 specifies which sources do not need to obtain a permit, and therefore do not need to undergo NSR review, even if their emissions are included in determining if a source is major.

The District’s comment refers to concerns that the EPA has expressed “in the past.” Although the EPA may have expressed concerns with a previous version of Rule 219, our review of the submitted version of Rule 219 did not identify any remaining concerns and found that the rule is approvable.¹¹ Therefore, we do not find it necessary to address the merits of the “backstops” involving District enforcement and State laws that the District asserts would mitigate such a problem.

Comment #4b (Use of the term “contract”): The District comments that

the EPA failed to sufficiently communicate a deficiency identified in our proposed action, specifically, that Rules 1302 and 1304 allow for the interchangeable use of the terms “contract” and “permit.” The District states that, had the EPA communicated this deficiency, the District could have provided assurances to the EPA to remove the deficiency. The District states that it can and will be able to provide a commitment to modify the deficient provisions in a subsequent local action, but it requests specific guidance from the EPA on whether it is appropriate to provide the EPA a commitment to modify at this time.

Response to Comment #4b (Use of the term “contract”): We do not interpret the District’s comment to assert a legal or technical basis that our proposed action to disapprove this rule is incorrect. The District states that the term “contract” was most likely inadvertently retained and that it can commit to modify the specific provisions to address the issue. We appreciate the District’s willingness to address this deficiency. It is not necessary for the District to provide additional commitments. Following this final action, the EPA remains available to discuss necessary revisions, with the goal of full approval of revisions to the District’s rules and a fully approved NSR program.

Comment #5: Regarding the second deficiency the EPA identified in the proposed rulemaking, the calculation procedures the District uses to determine the amount of offsets required in certain situations, the District first states that the EPA partially mischaracterizes Rule 1304(C)(2)(d) as a “potential to emit to new potential to emit after modification” calculation. According to the District, this provision is more correctly characterized as “current fully offset allowable emissions” to “potential new emissions.” The District further states that the provision was intended to only be used to reduce the amount of offsets needed as opposed to a determination of whether offsets are required. The District also states that the structure of its NSR regulation is designed to ensure that emissions reductions are greater than those required by the Federal CAA provisions, and to meet specific requirements of the California Clean Air Act and states that the *de minimis* provisions in CAA section 182 could result in increased emissions. The District states that the provision allowing for the use of SERs has been in active use within the District since 1993, and that over that time, the number and extent of NAAQS

exceedances has declined within its jurisdiction despite significant increases in economic activity and population. Therefore, the District states, the decline in NAAQS exceedances would not have occurred if its NSR program was not achieving reductions at least as stringent as those under strict CAA methodology. The District also states that “it has provided clear and convincing evidence in its Staff Report and elsewhere that the entire NSR Program as formulated requires not only BACT but also Offsets in a number of situations where they would not be required under a strict [Federal] CAA calculation methodology thus resulting in a more stringent set of requirements overall.” The District states that, despite its assertion of the adequacy of the current SIP submission, it would appreciate specific guidance regarding the type and nature of evidence the EPA would consider appropriate to show equivalent stringency with the requirements of the CAA.

Response to Comment #5: The EPA does not agree with the District’s comment. Preliminarily, the EPA notes that Rule 1303(B) imposes offset obligations for new or modified facilities that emit or have the potential to emit above specified thresholds “as calculated pursuant to District Rule 1304.”¹² Rule 1304, “New Source Review Emission Calculations,” sets forth “the procedures and formulas to calculate increases and decreases in emissions” to determine applicability of offset obligations and to calculate SERs, which are “reductions generated within the same facility.”¹³ Rule 1304(B)(1) specifies “General emission change calculations,” and Rule 1304(B)(2) specifies “Net Emissions Increase Calculations.” Notably, Rule 1304(B)(2)(c) provides that the net emissions increase calculation must subtract SERs “as calculated and verified pursuant to Section C below.” Rule 1304(C) specifies the calculation of SERs. The EPA proposed to disapprove Rule 1304(C)(2)(d). This provision applies to modification projects at existing major sources that involve emissions units that “have been previously offset in a documented prior permitting action.” Thus, Rule 1304(C)(2)(d) relates to the calculation of a net emissions increase to establish offset obligations.

¹⁰ 87 FR 72434 (November 25, 2022). Technical Support Document, “Notice of Proposed Rulemaking Revisions to the California State Implementation Plan, MDAQMD, NSR Rules 206, 219, 1300, 1301, 1302, 1303, 1304, 1305, 1306, 1402.” Page 13.

¹¹ See, “Email Communication between Gerardo Rios (EPA) and Brad Poiriez (District) on 3/28/2019,” Docket No. C.12, expressing concerns with a previous version of Rule 219 that is not the subject of this rulemaking. (We have since corrected the inadvertent omission of portions of document C.12 from the docket and we note that substantive portions of document No. C.12 were included in a different document, “Spreadsheet of identified deficiencies and changes made discussed during 11/17/20 Working Group Call with representatives from EPA, the District and CARB,” Docket No. C.15.) As we discussed in our proposed rule, and TSD section 5.7 and TSD Attachment 3, we found that Rule 219 as revised on January 25, 2021, and submitted to the EPA on July 23, 2019, to be consistent with CAA requirements.

¹² Rule 1303(B)(1). See also, EPA TSD at 17. Rule 1303(A) specifies control obligations, *i.e.*, Best Available Control Technology.

¹³ Rule 1304(A). In addition, Rule 1304 sets forth “procedures and formulas” to calculate BACT obligations. See Rule 1304 (A)(1)(a)(i). See also, EPA TSD at 17–18.

The EPA's proposed action explains that Rule 1304(C)(2)(d) is deficient because, for certain projects, it allows the amount of required offsets to be calculated using a pre-project baseline using potential emissions (generally, the emissions allowed by a permit),¹⁴ whereas the CAA requires a pre-project baseline based on actual emissions.¹⁵ As the EPA explained, CAA section 173(c)(1) requires the SIP to contain provisions to ensure that emission increases from new or modified major stationary sources are offset by real reductions in actual emissions. In addition, 40 CFR 51.165(a)(3)(ii)(J) requires that, for major modifications, the total quantity of increased emissions that must be offset shall be determined by summing the difference between the allowable emissions after the modification and the actual emissions before the modification for each emissions unit.

Rule 1304(C)(2)(d) is not consistent with statutory and regulatory requirements that the pre-project baseline utilize actual emissions to calculate offset obligations. Instead, for emissions from units that have been "previously offset in a documented prior permitting action," Rule 1304(C)(2)(d) allows the pre-project baseline to use the unit's potential to emit (the unit's allowable emissions) as reflected in a permit:

[Historic Actual Emissions] for a specific Emission Unit(s) may be equal to the Potential to Emit for that Emission Unit(s), [if] the particular Emissions Unit have [sic] been previously offset in a documented prior permitting action so long as: (i) The PTE for the specific Emissions Unit is specified in a Federally Enforceable Emissions Limitation; and (ii) The resulting Emissions Change from a calculation using this provision is a decrease or not an increase in emissions from the Emissions Unit(s) and (iii) Any excess SERs generated from a calculation using this provision are not eligible for banking pursuant to the provision [sic] of District Regulation XIV.

¹⁴ Rule 1304(C)(2)(d)(i) states that the PTE for an emissions unit is specified in a federally enforceable emissions limitation. Therefore, in the context of this rulemaking action, the terms "allowable" and "potential" are generally interchangeable.

¹⁵ We note that District's comment includes the following incorrect statement, "Specifically, USEPA is objecting to the use of Simultaneous Emissions Reductions (SERs) which are created as part and parcel of an NSR action at a Major Facility to in effect 'self-fund' the necessary offsetting emissions reductions by reducing emissions elsewhere in the Major Facility." The deficiency identified by the EPA is the District's calculation methodology to determine the quantity of offsets required, which inappropriately allows for the use of reductions that occurred in the past and are not necessarily "simultaneous."

The District states that the EPA partially mischaracterizes Rule 1304(C)(2)(d) as allowing the use of the potential-to-potential test because the provision is more correctly characterized as "current fully offset allowable emissions" to "potential new emissions." It is true that Rule 1304(C)(2)(d) allows the use of a pre-project baseline based on currently fully offset allowable emissions, because it is clear that the rule equates allowable emissions and potential to emit. However, the District's statements regarding the use of allowable emissions or potential emissions as the pre-project baseline are not relevant to the point presented in our proposed action: Rule 1304 is not consistent with Federal requirements because it does not require the use of *actual* emissions as the pre-project baseline, rather than allowable emissions.¹⁶

Allowable emissions are generally set higher than anticipated actual emissions to allow for normal fluctuations in emissions to occur without violating the permit conditions. The use of allowable emissions as the pre-project baseline means that the difference between pre-project and post-project emissions will be smaller than a calculation applying the EPA's requirement to use actual emissions as the pre-project baseline. Therefore, the District's rule, when using this provision, is likely to undercalculate the quantity of offsets required.

The District's assertion that only units that are already fully offset can use the allowable-to-potential offset quantification method does not remedy this deficiency, as fully offset units are still likely to have allowable emission limits above their actual emissions.¹⁷ Furthermore, the District's assertion that the allowable-to-potential methodology is only available to generate "self-

¹⁶ See, e.g., 40 CFR 51.165(a)(3)(ii)(J) [requiring offsets for each major modification at a major source in an amount equal to the difference between pre-modification *actual* emissions, not allowable (*i.e.*, potential) emissions].

¹⁷ Relatedly, Rule 1304(C)(d)(2) allows the use of allowable (*i.e.*, potential) emissions if the unit's emissions "have been previously offset in a documented permitting action," but does not specify a timeframe for such previous permitting actions, which is inconsistent with Rule 1304(B)(2)(c)'s provision that SERs must occur "at the same time or in connection with the same permitting action." The District's Staff Report also states, on pages 44–45: "If the Facility has fully offset Emissions Units it may in effect 'reuse' its previously provided offsets in a different capacity." CAA sections 173(a)(1)(A) and 173(c) and EPA's NSR regulations, however, do not allow facilities to use the same emissions reductions more than once; if a facility relies upon emissions reductions for a prior NSR action, under 40 CFR 51.165(a)(3)(ii)(G), they are not eligible for use again in a future NSR permit action.

funded" reductions for use as offsets also fails to remedy this problem, since Federal requirements require actual emissions to be used as the baseline for offsets calculations in all instances, including those in which a facility internally generates its own emissions reductions to satisfy its offset obligations. Similarly, the District's statement that its rule does not allow an increase in allowable emissions is irrelevant. CAA 173(c)(1) and 40 CFR 51.165(a)(3)(ii)(J) require that the quantity of offsets must be based on increases above actual emissions.

A real-world example that illustrates how the District's rules are less stringent than Federal requirements is a modification project reviewed by the District to upgrade three existing natural gas-fired combustion turbines at a power plant. The District's analysis of the project presents the facility's actual emissions of NO_x in the five-year period from 2016 to 2020 as ranging from 83.6 tons per year (tpy) to 103.9 tpy.¹⁸ The District's analysis also presents the "pre-modification PTE" of NO_x as 205 tpy. The District's analysis states that the "post-modification PTE" of NO_x is 204.5 tpy.¹⁹ Per the EPA's requirements, the required quantity of offsets for this project would be approximately 131 tpy (204.5 tpy minus the highest emissions rate of 103.9 tpy, multiplied by 1.3 for Severe nonattainment areas, as required under CAA section 182(d)(2)). Per the District's rules, however, the required quantity of offsets calculated is minimal because there is virtually no difference between pre-project allowable emissions and post-project allowable (*i.e.*, potential) emissions (in fact, the District's analysis indicates a 0.55 tpy decrease in emissions resulting from the project).²⁰

¹⁸ MDAQMD, "Preliminary Determination/Decision—Statement of Basis for Minor Modification to and Renewal of FOP Number: 104701849 For: High Desert Power Project, LLC." December 21, 2022, p. A–52 (PDF p. 72), Table 9.

¹⁹ MDAQMD, "Preliminary Determination/Decision—Statement of Basis for Minor Modification to and Renewal of FOP Number: 104701849 For: High Desert Power Project, LLC." December 21, 2022, p. A–54 (PDF p. 74), Table 14.

²⁰ See also, Letter dated June 16, 2022, from Jon Boyer, Director, Environmental, Health, and Safety, Middle River Power, to Lisa Beckham, EPA Region IX, Subject: "Prevention of Significant Deterioration (PSD) Applicability Analysis for Turbine Upgrades at the High Desert Power Project (Revised)." ("HDPP PSD Analysis"). The same project was analyzed as a modification under the Federal PSD program, which uses the baseline actual emissions to projected actual emissions methodology for determining applicability of the Federal NSR program. The submitted PSD analysis shows that the project will result in an increase in actual emissions. For NO₂, projected actual emissions would be 35.25 tpy greater than baseline actual emissions. HDPP PSD Analysis, Table 7, p. 8.

Regarding the District's statement that "USEPA is objecting to the use of Simultaneous Emissions Reductions (SERs) which are created as part and parcel of an NSR action at a Major Facility to in effect 'self-fund' the necessary offsetting emissions reductions by reducing emissions elsewhere in the Major Facility," the EPA disagrees. This statement is inaccurate because the EPA did not categorically reject the District's use of SERs; rather, we identified the District's SERs calculation methodology as inconsistent with Federal requirements.²¹ As has been noted, the EPA identified as a deficiency Rule 1304(C)(2)(d), which provides that the pre-project baseline can be equal to allowable (*i.e.*, potential to emit, or potential emissions) if the emissions unit has been "previously offset in a documented prior permitting action." Thus, the deficiency that the EPA identified is the District's use of SERs as a means to deviate from the Federal requirement to use actual emissions for the pre-project baseline. Instead, Rule 1304(C)(2)(d) uses a pre-project baseline using allowable (*i.e.*, potential) emissions for units with previously offset emissions. Moreover, the EPA's regulations at 40 CFR 51.165(a)(3)(ii)(J) plainly apply to each proposed major modification.

The District also states that SERs created from currently existing fully offset permit units at an existing major facility can only be used for changes at the same facility and cannot be banked. The fact that SERs cannot be bought and sold between facilities does not address the deficiency identified by the EPA that Rule 1304(C)(2)(d) allows the calculation of required offsets to use a baseline of allowable (*i.e.*, potential) emissions, not the federally required baseline of actual emissions.²²

The District also states that Rule 1304(C)(2)(d) is intended to be used only to reduce the amount of offsets needed as opposed to a determination of whether offsets are required. This statement, however, appears to be a distinction without a difference. For example, any scenario in which the District's calculation of the amount of offsets required is zero (as in the real-world example described above) is

tantamount to a determination that no offsets are required.

The District asserts "that it requires Best Available Control Technology (BACT) and offsets in more cases and on a greater number of Emissions Units" than the CAA requires. The District, however, provides no demonstration to support this claim, nor does the District provide any basis on which EPA could find that the District's NSR program ensures equivalency with Federal offset requirements.²³ Similarly, the references in the District's comment letter to its Staff Report are not sufficient to demonstrate that its NSR program offsets emissions increases in a manner that is at least as stringent as Federal requirements. For example, Table 4 of the Staff Report compares BACT and offset requirements, but the information does not demonstrate how implementation of the District's NSR program is imposing an equivalent quantity of offsets.²⁴ In addition, the last row of Table 4 states that offsets are required for significant modifications at existing major facilities, but it does not address the difference between the District's program and the Federal regulations in calculating the necessary quantity of offsets for such projects.

The District also asserts that the EPA previously approved the provision we now find deficient and that, since 1993, when this provision came into active use, the number and extent of NAAQS exceedances has declined. The District also asserts that the decline in emissions could not have occurred if its NSR program was not achieving reductions at least as stringent as those that would occur if the District followed the requirements of the CAA. We do not agree with this comment. NSR programs primarily regulate construction and modification of stationary sources, and improvements in air quality can and do result from regulation of existing stationary sources (*e.g.*, reasonably available control technology (RACT), reasonably available control measure (RACM), and best available control measure (BACM) requirements) as well as from regulation of mobile sources such as passenger vehicles and trucks, and non-road engines such as diesel engines used in agriculture and construction. The EPA also notes that the District is currently classified as Severe nonattainment for the 2008 and 2015 NAAQS; therefore, the CAA requires the District to implement rules consistent with Federal nonattainment NSR requirements at CAA section 173 and 40 CFR 51.165.

We address MDAQMD's point regarding the De Minimis provisions at CAA 182(c)(6) in response to Comments 9 and 10 below.

Comment #6: The District disagrees with the EPA's proposed disapproval of Rule 1301's definitions of the terms "Major Modification" and "Modification (Modified)." The District summarizes the EPA's concern that these terms allow the use of reductions from previously offset emissions units as SERs in such a way that a source might avoid entirely offset requirements. The District states that the EPA is correct that the Net Emissions Increase calculation under Rule 1304(B)(2)(c) includes SERs, but that the EPA failed to consider that Rule 1302 "very clearly sets out a flow for analysis in which one step occurs after another in sequence," referring to the "Final NSR Staff Report." The District also states that the EPA also failed to consider Rule 1303(A)(4), which excludes the use of SERs in determining emissions increases for the purpose of applying BACT.

The District admits that Rule 1304(C)(2)(d) could be interpreted incorrectly "without the procedural sequence that Rule 1302 sets forth." The District asserts that these provisions have been in active use since 1993 with demonstrable results in overall air quality. The District states that, despite its assertion of the adequacy of the submitted provisions, it would appreciate guidance from the EPA regarding methods to clarify that SERs derived from previously fully offset activities can be used only to reduce the amount of offsets required and not for any other purpose.

Response to Comment #6: The EPA disagrees with the District's assertions that the EPA's proposed disapproval of Rule 1301's definitions for "Major Modification" and "Modification (Modified)," is incorrect. We note that Rule 1301 defines both terms using the term "Net Emissions Increase," and, as explained in our proposed action, Rule 1301(QQ) defines the term "Net Emissions Increase" as an emission increase calculated per Rule 1304(B)(2) that exceeds zero.²⁵ Rule 1304(B)(2) prescribes the calculation methodologies for net emissions increases, and provides that net emissions increases must subtract SERs "as calculated and verified pursuant to Section C below."²⁶ As noted in our proposed action and in our response to Comment 5, Rule 1304(C)(2)(d) allows permit applicants to calculate a net

²¹ 87 FR 72434, 72437. We identified several District rules as not fully approvable because they do not ensure compliance with Federal regulations for calculation of required offsets, stemming from cross-references to Rule 1304(C)(2)(d). See, *e.g.*, TSD Table 4, "Summary of Deficiencies Due to Cross References."

²² Arguably, the District allows facilities to "bank" emission reductions for their own internal future use, even if the District prohibits use of banked emission reductions between facilities.

²³ See 40 CFR 51.165(a)(1), (a)(2)(ii).

²⁴ MDAQMD Staff Report p. 38–40.

²⁵ 87 FR 72434, 72437.

²⁶ Rule 1304(B)(2)(c).

emissions increase using allowable (*i.e.*, potential) emissions as the pre-project baseline, rather than actual emissions, as required by the EPA's regulations.²⁷ As we have explained in our response to Comment 5 above, the District's approach is less stringent than Federal requirements because actual emissions are almost always lower than allowable (*i.e.*, potential) emissions. Therefore, an evaluation of a net emissions increase (which is essentially a comparison of pre-project and post-project emissions) that uses actual emissions as the pre-project baseline (as required by the EPA's regulations) will show a higher net emissions increase than a calculation that uses allowable (*i.e.*, potential) emissions as the pre-project baseline.

We further note that Rule 1303, "New Source Review Requirements," sets forth Best Available Control Technology (BACT) requirements²⁸ at subsection (A), and subsections (A)(2) and (A)(3) impose BACT requirements through the use of the term "Modified," defined at Rule 1301(NN).²⁹ As we explained in our proposed action, Rule 1301(NN) defines "Modified" in terms of whether a project will result in a "Net Emissions Increase."³⁰ As a result, a project that does not result in a "Net Emissions Increase" will not meet the criteria for "Modified." Therefore, projects can potentially avoid the applicability of the BACT requirement because Rule 1303 uses the term "Modified" and, indirectly, the term "Net Emissions Increase," to impose this requirement.

Similarly, Rule 1303(B)(2) imposes offset requirements using the term "Major Modification," which is defined at Rule 1301(JJ). Rule 1301(JJ) defines "Major Modification" using the term "Net Emissions Increase."³¹ As a result, a project that does not result in a "Net Emissions Increase" will not meet the criteria for a "Major Modification" and therefore can potentially avoid the applicability of offset requirements because Rule 1303 uses the term "Major Modification" and, indirectly, the term

"Net Emissions Increase," to impose this obligation.

The District states, "the existence of Rule 1302 . . . very clearly sets out a flow for analysis in which one step occurs after another in sequence . . . First you determine 'Emissions Change' under 1302(C)(1) on both an Emission Unit and Facility wide basis using 1304(B)(1) . . . No SERs are used in this calculation." The EPA does not agree with these statements. Rule 1302(C)(1) does not specifically reference Rule 1304(B)(1)—it references, more generally, Rules 1304 and 1600.³² This point is significant because Rule 1302(C)(1)'s general cross-reference to Rule 1304 encompasses not just Rule 1304(B)(1), which might be helpful, but also the deficient provisions of Rule 1304(C)(2)(d), which, as explained above, calculate SERs using a pre-project baseline of allowable (*i.e.*, potential) emissions, which results in improper calculations of net emissions increases.

The District, in its comment letter, "admits that the provisions as expressed in 1304(C)(2)(d) could, in the abstract and absent the procedural sequence set forth in 1302, potentially be interpreted incorrectly." The EPA does not agree that Rule 1302 contains a "procedural sequence." We also do not find any such sequence in Rule 1304. Rule 1304 identifies several different types of emissions calculations but does not specify an analytical framework for their use.

The District's comment also repeatedly refers to its Staff Report. In general, references to non-regulatory sources can be helpful to explain regulatory text; however, the District's reliance on its Staff Report in this instance is not sufficient to correct the fact that the rules fail to ensure proper analysis and implementation of Federal requirements.

Therefore, Rule 1302's broad cross reference to Rule 1304 is insufficient to establish a sequence or an "analysis flow" such as that asserted by the District. The ambiguity in the District's rules means that they do not ensure a proper analysis of emissions changes, such as, for example, correctly evaluating whether a project will result in an "Emissions Change" before evaluating whether it will result in a "Net Emissions Increase." Such sequence is essential to correctly identifying whether a project would result in a net emissions increase under

40 CFR 51.165(a)(1)(vi), which the District currently uses as a basis for determining whether a project is a "Major Modification."

In reviewing SIP submissions, the EPA must ensure that the plain language of the rule under review is clear and unambiguous. In a September 23, 1987 memorandum, the "Potter memo," the EPA stated its criteria regarding the enforceability of SIPs and SIP revisions.³³ The Potter memo states that SIP rules must be clear in terms of their applicability, and that "[v]ague, poorly defined rules must become a thing of the past."³⁴ It also states that "SIP revisions should be written clearly, with explicit language to implement their intent. The plain language of all rules . . . should be complete, clear, and consistent with the intended purpose of the rules."³⁵ The EPA can only approve rule language that is clear on its face, and the sequence the District uses for determining emissions changes and net emissions increases is not sufficiently clear. The clarification in the Staff Report cannot supplant vague rule language. The District makes the statement that it has been using the provisions at issue "since 1993 with demonstrable results in overall air quality." Even if air quality improved during this period, the rules must be clarified to ensure they are interpreted properly. It is speculative to assume that any air quality improvements occurred as a result of the way the rules are currently written.

Additionally, the District's comment letter states that "USEPA also conveniently ignores the provisions of 1303(A)(4) which excludes the use of SERs in determining emissions increases for purpose [sic] of applying BACT." Rule 1303(A)(4) includes an appropriately specific cross-reference to Rule 1304(B)(1), regarding "General Emissions Change Calculations." Rule 1304(B)(1) provides for proper calculation of a project's emissions changes. However, the BACT requirement is also implemented by Rule 1303(A)(2) and (A)(3), which, as described above, use the term "Modified," which is problematically defined by Rule 1301(NN), specifically because of its cross-reference to the term "Net Emissions Increase," which is in turn deficient because of its cross-reference to Rule 1304's calculation

²⁷ 40 CFR 51.165(a)(2).

²⁸ We acknowledge that the District's definition of Best Available Control Technology in Rule 1301(J) is consistent with the definition of "lowest achievable emission rate" in CAA section 171(3) and 40 CFR 51.165(a)(1)(xiii).

²⁹ Rule 1303(A)(2) and (A)(3) use the term "Modified Permit Unit"; Rule 1301 separately defines the terms "Modification (Modified)" at subsection (NN) and "Permit Unit" at subsection (AAA).

³⁰ 87 FR 72437.

³¹ Rule 1301(JJ) refers to a "Significant Net Emissions Increase"; Rule 1301 separately defines "Significant" at subsection (NNN) and "Net Emissions Increase" at subsection (QQ).

³² Rule 1302(C)(1)(a) states: "The APCO shall analyze the application to determine the specific pollutants, amount, and change (if any) in emissions pursuant to the provisions of District Rules 1304 and 1600."

³³ Memorandum dated September 23, 1987, from J. Craig Potter, Assistant Administrator for Air and Radiation, to EPA Regional Administrators and Regional Counsels, Regions I–X, "Review of State Implementation Plans and Revisions for Enforceability and Legal Sufficiency."

³⁴ Id. at 3.

³⁵ Id. at 4.

methodologies, including Rule 1304(C)(2)(d). As we described in our response to Comment 5, the District determined that a project did not trigger BACT because there was no net emissions increase and therefore the facility was not “Modified” as defined in Rule 1301(NN). It appears that the District used the SERs-related provisions of Rule 1304(C)(2)(d) to calculate “Net Emission Increase” to conclude that the project was not “Modified” and as a result it did not require BACT.³⁶ We note that such a conclusion appears inconsistent with Rule 1303(A)(4), but apparently resulted from the ambiguities in Rules 1301, 1302, 1303, and 1304 described above. Under the District’s submitted NSR program, it is difficult to envision a scenario in which a “fully offset” emissions unit, using the District’s terminology, would ever need to install BACT or obtain offsets as long as the facility does not increase its allowable emissions. Therefore, we confirm the determinations in our proposed action that the definitions of “Modification (Modified)” and “Major Modification” in Rule 1301(QQ) and (NN) are deficient.

Comment #7: Regarding the EPA’s fourth identified deficiency, the use of the word “proceed” in the definition of “Historic Actual Emissions,” the District agrees that the deficiency is probably an overlooked typographical error, but that it has been in the rule for several iterations, dating back to 1996. The District states that it could have provided to the EPA a commitment to correct this deficiency prior to the publication of the EPA’s action if the EPA had provided prior notification of the issue. The District states that it would appreciate specific guidance from the EPA regarding whether a commitment to modify the deficient provision would be appropriate at this time.

Response to Comment #7: The District does not appear to disagree with the

EPA’s proposed determination that this issue is a deficiency; rather, the District appears to take issue with the way the EPA provided notification of it. The EPA appreciates the coordination and cooperation demonstrated over the period of joint work by our agencies to improve the District’s NSR rules. We remain available to discuss revisions necessary to address the deficiencies with the goal to full approval of revisions to the District’s rules and a fully approved NSR program. The District may address this deficiency, along with all other identified deficiencies, in its next revised SIP submittal of its NSR program rules.

Comment #8: This comment concerns the use of interprecursor trading, which is provided for in Rule 1305(C)(6). The District first states that the EPA is concerned that a court decision and subsequent change to 40 CFR 51.165(a)(11) make interprecursor trading impermissible. The District notes that it revised Regulation XIII (including Rule 1305) after the court decision but before the EPA revised 40 CFR 51.165(a)(11). The District states that it is unclear whether the revision to 40 CFR 51.165(a)(11) has been challenged and observes that the EPA could have chosen to revise the provision differently. The District states that the EPA did not provide any indication in the TSD on the current status of this particular regulatory provision other than a citation. The District references a footnote as providing sufficient warning and requiring compliance with the applicable provisions to ensure that interprecursor trading among ozone precursors does not occur in a subsequent NSR action. The District states that prompt communication on the EPA’s part “would have obliterated [sic] the need for this comment” as the District could have committed to clarifying the deficient provision in a subsequent rulemaking. The District then requests specific guidance from the EPA regarding whether the provision of a commitment to modify the deficient provision would be appropriate at this time.

Response to Comment #8: To the extent the District’s comment might be read as asserting that the EPA’s proposed limited approval/limited disapproval of Rule 1305 is incorrect, the EPA does not agree. As the District acknowledges in its comment, on January 29, 2021, the D.C. Circuit Court of Appeals issued a decision in *Sierra Club v. USEPA*, which vacated an EPA regulation that allowed the use of reductions of an ozone precursor to offset increases in a different ozone

precursor, *i.e.*, “interprecursor trading.”³⁷ On July 19, 2021, the EPA removed the ozone interprecursor trading provisions in 40 CFR 51.165(a)(11).³⁸

Rule 1305(C)(6) allows for the use of interprecursor trading. This fact is not changed by a footnote in the rule that acknowledges the January 2021 court decision without clearly prohibiting the use of interprecursor trading to satisfy offset obligations.³⁹ To the extent the District is suggesting that the timing of the EPA’s revisions to 40 CFR 51.165(a)(11) or the possibility of subsequent legal challenges to those revisions somehow affects the EPA’s conclusion that Rule 1305(C)(6) is not consistent with Federal law, we disagree. Therefore, the EPA’s proposed limited approval/limited disapproval of Rule 1305 is appropriate. Following this final action, the EPA remains available to discuss necessary revisions, with the goal of full approval of revisions to the District’s rules and a fully approved NSR program.

Comment #9: The District summarizes the EPA’s proposed action as asserting that CAA section 182(c)(6) “mandates the inclusion of a so called ‘De Minimis’ provision” and also as appearing to assert that CAA 182(c)(6) overrides the District’s ability to implement rules that are more stringent than the requirements of the CAA pursuant to CAA section 116. The District notes that the previous version of Rule 1303, as amended on September 24, 2001, contained a provision that satisfied this requirement, but that it removed the provision from the current version because it was unworkable. The District asserts that the EPA did not bring up this issue during the rule development period. The District states that the inclusion of the “de minimis” provision, as required under CAA section 182, would allow major facilities to increase their actual emissions without providing offsets, increasing NO_x and VOC emissions by as much as 750 tons per year. The District asserts that its removal of the “de minimis” provision from Rule 1303 strengthens the rule and results in its NSR program being more stringent than the CAA requirements. The District also states that, despite its assertion of the adequacy of the current submissions, it requests specific guidance regarding the

³⁷ See, *Sierra Club v. EPA*, 21 F.4th 815, 819–823 (D.C. Cir. 2021).

³⁸ 86 FR 37918 (July 19, 2021).

³⁹ The footnote attached to Rule 1305 states: “Use of this section subject to the ruling in *Sierra Club v. USEPA* (D.C. Cir. Case #15–1465 (1/29/2021), Document #1882662 and subsequent guidance by USEPA.”

³⁶ The District’s analysis of this project states: “The permitting action is classified as an NSR Modification as defined in Rule 1301(NN). As there are no net emissions increases associated with NO_x [nitrogen oxides], VOC [volatile organic compounds], or PM₁₀ [particulate matter], the emissions unit and the facility are *not* Modified as defined in Rule 1301 with respect to those pollutants and current BACT is not triggered.” (Emphasis in original.) MDAQMD, “Preliminary Determination/Decision—Statement of Basis for Minor Modification to and Renewal of FOP Number: 104701849 For: High Desert Power Project, LLC.” December 21, 2022, p. 8. We note that the District makes two logically inconsistent statements in its analysis of the project: first, that the project is an NSR Modification under Rule 1301(NN), and second, that the project is not Modified as defined in Rule 1301(NN).

type and nature of evidence the EPA would consider appropriate to show greater stringency of the District's NSR program than that provided by the "de minimis" provision.

Response to Comment #9: The EPA does not agree with the comment. CAA section 182(c)(6) ("the De Minimis Rule") specifies a mandatory requirement for state NSR programs in nonattainment areas classified as Serious and above.⁴⁰ It requires such areas to evaluate whether a particular physical change or change in the method of operation is a major modification by considering net emissions increases from that change and all other net emissions increases during the preceding five calendar years. If the total of all such increases is greater than 25 tons, the particular change is subject to the area's SIP-approved NNSR program, according to the plain text of CAA section 182(c)(6).

The District does not dispute the EPA's determination that the District's NSR program does not include provisions specified in CAA section 182(c)(6).⁴¹ Instead, the District asserts that the inclusion of language to satisfy the De Minimis Rule provision would result in emissions increases at major facilities, possibly totaling as much as 750 tons each of NO_x and VOC over a five-year period without requiring offsets. This assertion, however, reflects the District's misinterpretation of CAA 182(c)(6). CAA section 182(c)(6) requires NNSR programs in nonattainment areas to require facilities to aggregate project emissions over a *rolling* five-year period to ensure adequate regulatory review of NSR requirements such as those for control technologies and offsets. Contrary to the District's assertions, CAA section 182(c)(6) does not allow facilities to increase actual emissions by greater than 25 tons without offsetting them.

The District does not explain how the "no net increase" requirement of California Health and Safety Code section 40918(a)(1), which it references in footnote 73 of its comment letter, conflicts with the "De Minimis" requirements. The District's comment does not change the EPA's understanding that the De Minimis Rule operates independently of these requirements, and therefore the District's implementation of it would not weaken the District's current NNSR program. As the District's rules are

currently written, BACT requirements apply when an emission unit has an emission increase or PTE of greater than 4.56 tpy (25 lb/day) (Rule 1303(A)(1) and (2)), or when the emission increase or PTE of all emission units exceed 25 tpy (Rule 1303(A)(3)). For example, a new facility with five emission units, each with a PTE of 4 tpy, would not be subject to BACT requirements under state or Federal NSR requirements. However, if during the next five years, the source proposed to add three additional emission units, each with a PTE of 4 tpy, BACT would still not be triggered under the current rule, since the State 4.56 tpy emission unit and the Federal 25 tpy project thresholds have not been exceeded. However, under the "De Minimis" requirements, the new project would be considered a major modification, with an aggregated emission increase of 32 tpy, and therefore, trigger both BACT and offset requirements for the current project. This is because the aggregated emissions from the two projects occurring within a five-year time frame exceed the 25 tpy threshold. The District's rules fail to ensure that such a scenario is not treated as de minimis, as CAA section 182(c)(6) requires. The Federal De Minimis Rule prevents a series of smaller projects, with emissions equivalent to the major modification threshold, from avoiding the major modification requirements of BACT and offsets. California law does not ensure conformity with the De Minimis Rule; therefore, the District's NSR program must include provisions to ensure compliance with it.

The District asserts that its submitted rules would be more stringent than implementing the De Minimis Rule and other aspects of EPA's NNSR requirements and seeks guidance from the EPA on how to make this demonstration. In general, to make a demonstration that a program is at least as stringent as Federal NNSR program requirements, the District would need to demonstrate that the requirements of its rule would trigger LAER and offsets requirements in all cases that would trigger these same requirements pursuant to the provisions of CAA section 182(c)(6). The EPA does not believe such a demonstration is possible, given the variety of project scenarios, which, depending on the facts (timing and emission rates from individual groups of emission units), would show that each set of rules is more and less stringent than the other in some cases. As we discussed in our responses to Comments 5 and 6, the District's rules are flawed in that they

allow for improper calculation of net emissions increases, which affects the implementation of NSR requirements. Our responses to Comments 5 and 6 also describe the District's analysis of a permit application for a project involving a power plant and its determination that the project was not a modification because it would result in an emissions decrease, even though the project would increase actual emissions. We do not agree that the District's approach of not considering this project or other similar projects to be a modification constitutes a more stringent program.

As to the District's statement regarding the EPA not raising this issue earlier, the EPA appreciates the coordination and cooperation demonstrated over the period of joint work by our agencies to improve the rules. We remain available to discuss revisions necessary to address the deficiencies with the goal of full approval of revisions to the District's rules and a fully approved NSR program.

Comment #10: The District states that the De Minimis Rule "would have a profound negative effect on air quality" because not only would facilities be able to increase allowable emissions by up to 25 tons per rolling five-year period, but the rule would also cause other detrimental practices such as "emissions spiking" and delayed equipment upgrades.

Response to Comment #10: The District's hypothetical assertions that CAA 182(c)(6) would encourage "emissions spiking" to artificially increase actual emissions prior to making a modification are unsupported. As a practical matter, a source operating for two years above its actual needed operations to get as close as possible to its allowable emissions would likely incur significant costs in the process to unnecessarily operate the equipment. We do not see this scenario as providing a realistic incentive, in fact, implementation of CAA section 182(c)(6) would create no greater incentive for a source to increase its actual emissions prior to making a change that may require the source to undergo NNSR than the limited incentive that exists under the District's current rules. Similarly, the District's hypothetical assertion that the De Minimis Rule would discourage facilities from upgrading equipment is outside the scope of our proposed action, which is to ensure the District's NSR rules comply with Federal NNSR program requirements regarding the calculation of emission reductions and

⁴⁰ Nonattainment area classifications for the ozone NAAQS are established under CAA section 181.

⁴¹ The District also concedes that it revised Rule 1303 to remove a provision that previously provided such assurance.

the quantity of offsets required for significant emission increases.⁴²

The District requests that the EPA “provide clear and convincing evidence that the implementation of USEPA’s suggested corrections would indeed produce a benefit to air quality in the region”; however, the objective of the EPA review of the District’s submitted rules is to ensure conformity with Federal requirements. Our proposed action describes the statutory and regulatory requirements that the District’s NSR rules must satisfy for EPA approval.⁴³ Where the District disagrees with the EPA’s finding of deficiency, it has not provided a quantitative or legal demonstration that its rule provisions are more stringent, or at least as stringent as the Federal requirements.

Comment #11: The District states that the EPA’s proposed limited disapproval of all rules that cite Rule 1304(C)(2) is overbroad. The District states that the EPA has indicated that it is proposing to disapprove MDAQMD Rules 1301, 1302, 1303, 1304, and 1305 primarily due to the cross-references in these rules to provisions in Rule 1304(C)(2). The District states that such an action would disapprove the use of any internal offsetting for any facility—not just Major Facilities—regardless of the calculation used to determine SERs. The District states that such a disapproval might result in an increase of emission reduction credits being banked and then immediately used, under District Regulation XIV, “Emission Reduction Credit Banking,” but asserts that it is more probable that it would result in an immediate cessation of all modifications to existing facilities within the District. Therefore, the District states this action is overbroad, as simply disapproving the use of the provisions in Rule 1304(C)(2)(d) would be enough to alleviate the EPA’s stated concerns and allow the remainder of the NSR program to be approved in a manner and to the extent that it could be included to satisfy the 70 parts per billion (ppb) ozone NAAQS requirements. The District requests that the EPA provide further justification on why a more limited disapproval of the provisions contained in Rule 1304(C)(2)(d) would be insufficient to address the EPA’s major alleged deficiencies, as set forth in the EPA’s proposed action.

⁴² We also note that the District’s current NSR program fails to adequately address increases in actual emissions that might result from delayed equipment upgrades because the rules allowing net emissions increases to be evaluated using a baseline of pre-project allowable emissions rather than actual emissions. See EPA responses to Comments 5 and 6 above.

⁴³ See 87 FR 72437–38; TSD p. 8–9.

Response to Comment #11: As we stated in our proposed action, the deficiencies pertaining to offsets in the District’s NSR program make portions of Rules 1301, 1302, 1303, 1304, and 1305 not fully approvable because the District’s NSR program is not consistent with CAA section 182(c)(6). Our basis for that finding is also explained in our responses to Comments 9 and 10 above. In addition, the EPA’s TSD provides additional information regarding the deficiencies in these rules, largely as a result of cross references to Rule 1304(C)(2)(d), which allows SERs to be calculated using a baseline of allowable emissions, not actual emissions. This deficiency affects the calculation of net emissions increases in Rule 1304(B)(2). Therefore, the use of the term “net emissions increase” or cross-references to Rule 1304 also affect the approvability of Rules 1301, 1302, 1303, and 1305. Please see Table 4 of our TSD for additional information.

The EPA’s action to finalize a limited approval and limited disapproval of District Rules 1301, 1302, 1303, 1304, and 1305 into the SIP means that the rules, as currently submitted, will be incorporated into the SIP, but they must be revised and resubmitted to the EPA to avoid sanctions and FIP consequences. As we stated in our proposed action, we proposed limited approval and limited disapproval of these rules because although they fulfill most of the relevant CAA requirements and strengthen the SIP, they also contain certain deficiencies. Our final action incorporates into the SIP the submitted rules listed in Table 2 of this document for which we are fully approving or finalizing a limited approval/limited disapproval, including those provisions we identified as deficient.

III. EPA Action

None of the submitted comments change our assessment of the submitted rules as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving the submitted versions of Rules 206, 219, 1300, 1306, and 1402. Likewise, as authorized under sections 110(k)(3) and 301(a) of the Act, the EPA is finalizing a limited approval of the submitted versions of Rules 1301, 1302, 1303, 1304, and 1305. This action incorporates submitted Rules 206, 219, 1300, 1301, 1302, 1303, 1304, 1305, 1306, and 1402 into the California SIP, including those provisions identified as deficient. As authorized under section 110(k)(3) and 301(a), the EPA is simultaneously finalizing a limited

disapproval of Rules 1301, 1302, 1303, 1304, and 1305.

As a result of our limited approval and limited disapproval of Rules 1301, 1302, 1303, 1304, and 1305, the EPA must promulgate a Federal implementation plan (FIP) under section 110(c) for the West Mojave Desert nonattainment area portion of the District within 24 months unless we approve subsequent SIP revisions that correct the deficiencies identified in this action. In this instance, we note that the EPA already has an existing obligation to promulgate a FIP for any NSR SIP elements that we have not taken final action to approve.⁴⁴ In addition, the offset sanction in CAA section 179(b)(2) will be imposed 18 months after the effective date of this action, and the highway funding sanction in CAA section 179(b)(1) six months after the offset sanction is imposed. Sanctions will not be imposed if the EPA approves a subsequent SIP submission that corrects the identified deficiencies before the applicable deadlines.

In this action we are also finalizing an approval of the District’s visibility provisions for major sources subject to review under the NNSR program under 40 CFR 51.307. Therefore, we are revising 40 CFR 52.281(d) to remove the FIP for visibility protections as it applied to the District.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is incorporating by reference the District rules listed in Table 2 of this preamble which implement the District’s New Source Review (NSR) permitting program for new and modified sources of air pollution under part D of title I of the CAA.⁴⁵ The EPA has made, and will continue to make, these materials available through <https://www.regulations.gov> and in hard copy

⁴⁴ The FIP obligation originates from our February 3, 2017 finding that the District failed to submit a Nonattainment NSR SIP for the 2008 8-hour ozone NAAQS by the required submittal deadline. This finding of failure to submit established a FIP obligation deadline of March 6, 2019. See also, *CBD v. Regan*, N.D. Cal. 22–cv–3309.

⁴⁵ In the IBR section of our proposed action (87 FR 72434) we inadvertently referred to Table 1 as opposed to Table 2 for the list of submitted rules that are intended to replace the rules in the SIP. However, we explained in Section C of our proposed action that “the rules listed in Table 2 are intended to replace the SIP-approved rules listed in Table 1.” We also stated in Section F of our proposed action that, “[i]f finalized, this action would incorporate into the SIP the submitted rules listed in Table 2 for which we have proposed approval or limited approval/limited disapproval”

at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by State law.

C. Regulatory Flexibility Act (RFA)

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

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by State law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

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

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has

demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by State law.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” EPA further defines the term fair treatment to mean

that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.”

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA’s role is to review state choices, and approve those choices if they meet the minimum criteria of the Act. Accordingly, this final action is finalizing the approval and the limited approval and limited disapproval of a state submittal as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law.

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

K. Congressional Review Act (CRA)

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

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 29, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

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

Dated: June 16, 2023.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the
preamble, the Environmental Protection
Agency amends part 52, chapter I, title
40 of the Code of Federal Regulations 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 F—California

■ 2. Section 52.220 is amended by:

- a. Adding paragraphs (c)(31)(vi)(G)
and (H), (c)(32)(iv)(G), (c)(39)(ii)(K) and
(L), (c)(39)(iv)(K), (c)(68)(iii) and (iv),
(c)(70)(i)(E), (c)(87)(iv)(B),
(c)(103)(xviii)(C), (c)(155)(iv)(C),
(c)(224)(i)(C)(3), (c)(239)(i)(A)(4), and
(c)(248)(i)(D)(3);
- b. Adding reserved paragraphs
(c)(598) and (599); and
- c. Adding paragraphs (c)(600) and
(601).

The additions read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *
(31) * * *
(vi) * * *

(G) Previously approved on November
9, 1978, in paragraph (c)(31)(vi)(C) of
this section and now deleted with
replacement in paragraph
(c)(601)(i)(A)(1) of this section for
implementation in the Mojave Desert
Air Quality Management District: Rule
206.

(H) Previously approved on November
9, 1978, in paragraph (c)(31)(vi)(C) of
this section and deleted with
replacement in paragraph
(c)(103)(xviii)(A) of this section: Rule
219.

* * * * *

(32) * * *
(iv) * * *

(G) Previously approved on November
9, 1978, in paragraph (c)(32)(iv)(C) of

this section and deleted with
replacement in paragraph
(c)(103)(xviii)(A) of this section: Rule
219.

* * * * *

(39) * * *
(ii) * * *

(K) Previously approved on November
9, 1978, in paragraph (c)(39)(ii)(B) of
this section and now deleted with
replacement in paragraph
(c)(601)(i)(A)(1) of this section: Rule
206.

(L) Previously approved on November
9, 1978, in paragraph (c)(39)(ii)(B) of
this section and now deleted with
replacement in paragraph
(c)(600)(i)(A)(1) of this section: Rule
219.

* * * * *

(iv) * * *

(K) Previously approved on November
9, 1978, in paragraph (c)(39)(iv)(B) of
this section and deleted without
replacement for implementation in the
Mojave Desert Air Quality Management
District: Rules 206 and 219.

* * * * *

(68) * * *

(iii) Previously approved on January
21, 1981, in paragraph (c)(68)(i) of this
section and deleted with replacement in
paragraph (c)(239)(i)(A)(1) of this
section for implementation in the
Mojave Desert Air Quality Management
District: Rules 1301, 1303, 1304, 1306,
1307, 1310, 1311, and 1313.

(iv) Previously approved on January
21, 1981, in paragraph (c)(68)(i) of this
section and deleted with replacement in
paragraph (c)(155)(iv)(B) of this section:
Rule 1305.

* * * * *

(70) * * *

(i) * * *

(E) Previously approved on January
21, 1981, in paragraph (c)(70)(i)(A) of
this section and deleted with
replacement in paragraph
(c)(239)(i)(A)(1) of this section for
implementation in the Mojave Desert
Air Quality Management District: Rules
1302 and 1308.

* * * * *

(87) * * *

(iv) * * *

(B) Previously approved on June 9,
1982, in paragraph (c)(87)(iv)(A) of this
section and deleted with replacement in
paragraph (c)(239)(i)(A)(1) of this
section: Rules 1301, 1302, 1303, 1304,
1305, 1306, 1307, 1308, 1310, 1311, and
1313.

* * * * *

(103) * * *
(xviii) * * *

(C) Previously approved on July 6,
1982, in paragraph (c)(103)(xviii)(A) of

this section and now deleted with
replacement in paragraph
(c)(600)(i)(A)(1) of this section for
implementation in the Mojave Desert
Air Quality Management District: Rule
219.

* * * * *

(155) * * *

(iv) * * *

(C) Previously approved on January
29, 1985 in paragraph (c)(155)(iv)(B) of
this section and deleted with
replacement in paragraph
(c)(239)(i)(A)(1) of this section for
implementation in the Mojave Desert
Air Quality Management District: Rule
1305.

* * * * *

(224) * * *

(i) * * *

(C) * * *

(3) Previously approved on January
22, 1997, in paragraph (c)(224)(i)(C)(1)
of this section and now deleted with
replacement in paragraph
(c)(248)(i)(D)(3) of this section: Rule
1402, adopted on June 28, 1995.

* * * * *

(239) * * *

(i) * * *

(A) * * *

(4) Previously approved on November
13, 1996, in paragraph (c)(239)(i)(A)(1)
of this section and now deleted with
replacement in paragraphs
(c)(600)(i)(A)(2) through (8) of this
section: Rules 1300, 1301, 1302, 1303,
1304, 1305, and 1306, adopted on
March 25, 1996.

* * * * *

(248) * * *

(i) * * *

(D) * * *

(3) Rule 1402, “Emission Reduction
Credit Registry,” amended on May 19,
1997.

* * * * *

(598) [Reserved]

(599) [Reserved]

(600) The following regulations were
submitted on July 23, 2021, by the
Governor’s designee as an attachment to
a letter dated July 22, 2021.

(i) *Incorporation by reference.* (A)
Mojave Desert Air Quality Management
District.

(1) Rule 219, “Equipment Not
Requiring a Permit,” amended on
January 25, 2021.

(2) Rule 1300, “New Source Review
General,” amended on March 22, 2021.

(3) Rule 1301, “New Source Review
Definitions,” amended on March 22,
2021.

(4) Rule 1302, “New Source Review
Procedure,” (except subsections (C)(5)
and (C)(7)(c)), amended on March 22,
2021.

(5) Rule 1303, “New Source Review Requirements,” amended on March 22, 2021.

(6) Rule 1304, “New Source Review Emissions Calculations,” amended on March 22, 2021.

(7) Rule 1305, “New Source Review Emission Offsets,” amended on March 22, 2021.

(8) Rule 1306, “New Source Review for Electric Energy Generating Facilities,” amended on March 22, 2021.

(B) [Reserved]

(ii) [Reserved]

(601) The following regulations were submitted on October 15, 2021, by the Governor’s designee as an attachment to a letter dated October 14, 2021.

(i) *Incorporation by reference.* (A) Mojave Desert Air Quality Management District.

(1) Rule 206, “Posting of Permit to Operate,” amended on February 22, 2021.

(2) [Reserved]

(B) [Reserved]

(ii) [Reserved]

■ 3. Section 52.281 is amended by revising paragraph (d) introductory text and adding paragraph (d)(9) to read as follows:

§ 52.281 Visibility protection.

* * * * *

(d) *Plan provisions.* The provisions of § 52.28 are hereby incorporated and made part of the applicable plan for the State of California, except for the air pollution control districts listed in this paragraph (d). The provisions of § 52.28 remain the applicable plan for any Indian reservation lands, and any other area of Indian country where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, located within the State of California, including any such areas located in the air pollution control districts listed in this paragraph (d).

* * * * *

(9) Mojave Desert Air Quality Management District.

* * * * *

[FR Doc. 2023–13393 Filed 6–29–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 230626–0155]

RIN 0648–BL58

Reef Fish Resources of the Gulf of Mexico and Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; Conversion of Historical Captain Permits

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

ACTION: Final rule.

SUMMARY: NMFS implements management measures as described in an abbreviated framework action under the Fishery Management Plans (FMPs) for the Reef Fish Resources of the Gulf of Mexico (Reef Fish FMP) and Coastal Migratory Pelagic (CMP) Resources of the Gulf of Mexico and Atlantic Region (CMP FMP). This final rule will enable a permit holder to replace a historical captain endorsement in the reef fish and CMP fisheries in the Gulf of Mexico (Gulf) with a standard Federal charter vessel/headboat permit in the same Gulf fisheries. NMFS expects that this final rule will reduce the potential regulatory and economic burden on historical captain permit holders.

DATES: This final rule is effective on July 31, 2023.

ADDRESSES: An electronic copy of the abbreviated framework document that contains an environmental assessment and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office website at <https://www.fisheries.noaa.gov/action/framework-action-historical-captain-permits-conversion-standard-federal-charter-headboat>. The proposed rule for this action can be downloaded from the same NMFS website or from www.regulations.gov by searching “NOAA–NMFS–2022–0121.”

FOR FURTHER INFORMATION CONTACT: Rich Malinowski, NMFS Southeast Regional Office, telephone: 727–824–5305, email: rich.malinowski@noaa.gov.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico Fishery Management Council (Gulf Council) manages reef fish in Gulf Federal waters under the Reef Fish FMP. In Gulf and Atlantic Federal waters, the Gulf Council and South Atlantic Fishery Management Council (Councils) jointly manage CMP species

under the CMP FMP. The Gulf Council prepared the Reef Fish FMP and the Councils jointly prepared the CMP FMP. NMFS implements the FMPs through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*).

On January 27, 2023, NMFS published a proposed rule in the **Federal Register** for the abbreviated framework action and requested public comment (88 FR 5295). The proposed rule and the abbreviated framework action outline the rationale for the action contained in this final rule. A summary of the management measure described in the abbreviated framework action and implemented by this final rule is provided below.

Management Measure Contained in This Final Rule

This final rule enables a permit holder with an eligible historical captain endorsement in the Gulf reef fish or Gulf CMP fishery to convert that endorsement to a standard Federal charter vessel/headboat permit (for-hire permit) in the same Gulf fishery, as applicable. This rule also extends the same rights and responsibilities of these standard for-hire permits to eligible individuals who choose to convert a historical captain endorsement to a standard for-hire permit. An eligible historical captain endorsement is hereafter referenced in this preamble as a historical captain permit. There are currently four historical captain permits, two for Gulf reef fish and two for Gulf CMP species, and are held by two individuals. Historical captain permits cannot be transferred to another person and no additional historical captain permits can be issued (50 CFR 622.20(b)(1)(i)(B); 85 FR 22043, April 21, 2020).

If an individual with an eligible historical captain permit wants to convert the permit to a standard for-hire permit, the individual must submit an application for a standard for-hire permit to NMFS along with their current, original historical captain permit (not a copy), and all supporting documents and fees, including documentation for the vessel to which NMFS will issue or associate with the standard for-hire permit. Unlike a historical captain permit, which is issued to an individual, a standard for-hire permit must be issued to a vessel with a valid U.S. Coast Guard certificate of documentation or state registration certificate (50 CFR 622.4(a)). If the permit applicant is the owner of the vessel, NMFS’ Permits Office staff will

verify that the vessel for which the new standard for-hire permit will be issued is owned by the applicant and does not have an existing Gulf reef fish or CMP charter vessel/headboat permit associated with it, as vessels are not allowed to have multiple charter vessel/headboat permits of the same type associated with them.

If the vessel to which the permit will be associated with is to be leased, a fully executed lease agreement of at least 7 months between the vessel owner and permit holder will need to be included with the application. Note that vessel owners and lessees cannot hold permits issued to the same vessel at the same time. NMFS' Permits Office staff will then verify the vessel does not have any other Federal permit associated with it in another permit holder's name.

After NMFS verifies that the information provided with the application allows for the conversion, the historical captain permit will then be converted to a standard for-hire permit for Gulf reef fish or Gulf CMP species, as applicable. Historical captain permit numbers are unique, and the new standard for-hire permit will keep the existing permit number (*e.g.*, HRCG-9999 will convert to RCG-9999). A standard for-hire permit issued as a result of this final rule will have the same passenger capacity limitation as the historical captain permit that it will replace.

Comments and Responses

NMFS received two public comments supporting the proposed rule for the abbreviated framework action. NMFS acknowledges the comments in favor of the action in the proposed rule. One commenter also suggested that NMFS reduce or waive the fee to convert a historical captain permit to a standard for-hire permit. However, this suggestion is beyond the scope of the action considered in the proposed rule, and we do not address it further in this final rule. NMFS made no changes to the final rule resulting from public comments.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this final rule is consistent with the abbreviated framework action, the FMPs, the Magnuson-Stevens Act, and other applicable laws.

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

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting

Federal rules have been identified. A description of this final rule, why it is being implemented, and the purpose of this final rule are contained in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of this final rule.

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

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

List of Subjects in 50 CFR Part 622

Fish, Fisheries, Gulf of Mexico, Historical captain, Permit, Transfer.

Dated: June 26, 2023.

Samuel D. Rauch, III,
*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

For the reasons set out in the preamble, NMFS amends 50 CFR part 622 as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.20, revise paragraph (b)(1)(v) to read as follows:

§ 622.20 Permits and endorsements.

* * * * *

(b) * * *

(1) * * *

(v) *Procedure for conversion of permit with historical captain endorsement.* A charter vessel/headboat permit with a historical captain endorsement may be converted to a charter vessel/headboat permit for Gulf reef fish without a historical captain endorsement. A charter vessel/headboat permit with a historical captain endorsement that is converted to a charter vessel/headboat permit without a historical captain endorsement will retain the same vessel permit maximum passenger capacity as the permit it replaces. To convert an eligible charter vessel/headboat permit with a historical captain endorsement, the permit holder must submit a permit

application to the RA by July 30, 2025. If no application to convert an eligible charter vessel/headboat permit with a historical captain endorsement is submitted by July 30, 2025, the permit holder will retain a charter vessel/headboat permit with the historical captain endorsement that is subject to the restrictions described in paragraph (b)(1)(i)(B) of this section.

* * * * *

■ 3. In § 622.373, revise paragraph (f) to read as follows:

§ 622.373 Limited access system for charter vessel/headboat permits for Gulf coastal migratory pelagic fish.

* * * * *

(f) *Procedure for conversion of permit with historical captain endorsement.* A charter vessel headboat permit with a historical captain endorsement may be converted to a charter vessel/headboat permit for Gulf coastal migratory pelagic fish without a historical captain endorsement as described in paragraph (b)(1) of this section. A charter vessel/headboat permit with a historical captain endorsement that is converted to a charter vessel/headboat permit without a historical captain endorsement will retain the same vessel permit maximum passenger capacity as the permit it replaces. To convert an eligible charter vessel/headboat permit with a historical captain endorsement, the permit holder must submit a permit application to the RA by July 30, 2025. If no application to convert an eligible charter vessel/headboat permit with a historical captain endorsement is submitted by July 30, 2025, the permit holder will retain a charter vessel/headboat permit with the historical captain endorsement that is subject to the restrictions described in paragraph (b)(2) of this section.

[FR Doc. 2023-13925 Filed 6-29-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 220919-0193]

RTID 0648-XD085

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries; General Category Retention Limit Adjustment

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; retention limit adjustment.

SUMMARY: NMFS is adjusting the General category daily retention limit from three large medium or giant (*i.e.*, measuring 73 inches (185 cm) curved fork length (CFL) or greater) Atlantic bluefin tuna (BFT) to one large medium or giant BFT. This daily retention limit applies to Atlantic Tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT. This adjustment will be effective for the remainder of the June through August time period.

DATES: Effective July 2, 2023, through August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Erianna Hammond, erianna.hammond@noaa.gov, 301-427-8503, or Larry Redd, Jr., larry.redd@noaa.gov, 301-427-8503.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

As described in § 635.27(a), the current baseline U.S. BFT quota is 1,316.14 metric tons (mt) (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). The General category baseline quota is currently 710.7 mt. This baseline quota is further subdivided into subquotas by time period. The baseline subquota for the June through August time period is 355.4 mt. The default General category

daily retention limit is one large medium or giant (*i.e.*, measuring 73 inches (185 cm) CFL or greater) BFT per vessel per day/trip and applies to General category permitted vessels and to HMS Charter/Headboat permitted vessels (when fishing commercially for BFT) (§ 635.23(a)(2)). NMFS adjusted the daily retention limit adjustment for the beginning of the June through August 2023 time period from the default daily retention limit of one to three large medium or giant BFT (88 FR 34454, May 30, 2023). This action would adjust the daily retention limit back to one large medium or giant BFT for the remainder of the June through August 2023 time period.

Adjustment of General Category Daily Retention Limit

Under § 635.23(a)(4), NMFS may increase or decrease the daily retention limit of large medium and giant BFT over a range of zero to five BFT per vessel after considering the regulatory determination criteria under § 635.27(a)(7).

NMFS has considered all of the relevant determination criteria and their applicability to the General category BFT retention limit for June through August 2023. As described below, after considering these criteria, NMFS has decided to decrease the daily retention limit from three to one large medium or giant BFT per vessel per day/trip (*i.e.*, one BFT measuring 73 inches (185 cm) CFL or greater) for General category permitted vessels and for HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT. HMS Charter/Headboat permitted vessels fishing recreationally under the Angling category restrictions must follow the Angling category retention and size limits.

Regardless of the duration of a fishing trip, the daily retention limit applies upon landing. For example (and specific to the June through August 2023 limit), whether a vessel fishing under the General category retention limit takes a 2-day trip or makes two trips in 1 day, the daily limit of one fish may not be exceeded upon landing. This General category retention limit is effective in all areas, except for the Gulf of Mexico, where NMFS prohibits targeting fishing for BFT, and applies to those vessels permitted in the General category, as well as to those HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

Consideration of the Determination Criteria

As described above, under § 635.23(a)(4), NMFS may adjust the daily retention limit of large medium and giant BFT after considering the regulatory determination criteria under § 635.27(a)(7). Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(7)(i)), biological samples collected from BFT landed by General category fishermen and provided by BFT dealers continue to provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT would support the continued collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the General category quota to date and the likelihood of closure of the General category if no adjustment is made (§ 635.27(a)(7)(ii)). Commercial-size BFT are currently readily available to vessels fishing under the General category quota. To date, the General category has landed approximately 27.4 mt, representing 8 percent of the General category June through August time period. If current catch rates continue with the three-fish daily limit, the available for the June through August time period will be reached or exceeded, and NMFS would need to close the fishery earlier than otherwise would be necessary under a lower limit. NMFS intends to provide General category participants in all areas and time periods opportunities to harvest the General category quota without exceeding it, through active inseason management such as retention limit adjustments and/or the timing and amount of quota transfers (based on consideration of the determination criteria regarding inseason adjustments), while extending the season as long as practicable. NMFS is setting the limit for the remainder of the June through August 2023 time period in such a way that NMFS believes, informed by past experience, increases the likelihood that the fishery will remain open throughout the June through August time period and year.

NMFS also took into consideration a recently published final rule that would set restricted-fishing days (RFDs) for the General category during the months of July through November 2023, with the first RFD scheduled for July 1 (88 FR 33839, June 1, 2023). On an RFD, General category permitted vessels and

HMS Charter/Headboat permitted vessels (when fishing commercially for BFT) are prohibited from fishing for BFT. However, HMS Charter/Headboat permitted vessels are authorized to fish recreationally under the Angling category restrictions and must follow the Angling category BFT retention and size limits. NMFS believes the final RFD action, in combination with reducing the daily retention limit that applies on open days (through this inseason action) would further increase the likelihood that the fishery would remain open throughout the June through August time period and year.

NMFS also considered the effects of the adjustment on the BFT stock and the effects of the adjustment on accomplishing the objectives of the 2006 Consolidated HMS FMP (§ 635.27(a)(8)(v) and (vi)). This retention limit adjustment would be consistent with established quotas and subquotas, which are implemented consistent with ICCAT Recommendation 22–10, ATCA, and the objectives of the 2006 Consolidated HMS FMP and amendments. In establishing these quotas and subquotas and associated management measures, ICCAT and NMFS considered the best scientific information available, objectives for stock management and status, and effects on the stock. This retention limit adjustment is in line with the established management measures and stock status determinations. It is also important that NMFS be consistent with and limit landings to the subquotas both to adhere to the subquota allocations and to ensure that landings are as consistent as possible with the pattern of fishing mortality (e.g., fish caught at each age) that was assumed in the latest stock assessment. This retention limit adjustment is consistent with all of the above listed objectives.

Another principal consideration in setting the retention limit is the objective of providing opportunities to harvest the available General category quota without exceeding the annual quota. This consideration is based on the objectives of the 2006 Consolidated HMS FMP and its amendments, and includes achieving optimum yield on a continuing basis and optimizing the ability of all permit categories to harvest available BFT quota allocations (related to § 635.27(a)(7)(x)).

Given these considerations, NMFS has determined that a one-fish General category retention limit is warranted for the remainder of the June through August 2023 time period. This retention limit would provide a reasonable opportunity to harvest the available U.S.

BFT quota (including the expected increase in available 2023 quota based on 2022 underharvest), without exceeding it, while maintaining an equitable distribution of fishing opportunities; help optimize the ability of the General category to harvest its available quota; allow the collection of a broad range of data for stock monitoring purposes; and be consistent with the objectives of the 2006 Consolidated HMS FMP and amendments.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat vessel owners are required to report their own catch of all BFT retained or discarded dead, within 24 hours of the landing(s) or end of each trip, by accessing www.hmspermits.noaa.gov or by using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available quota is not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access www.hmspermits.noaa.gov, for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act and regulations at 50 CFR part 635 and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that pursuant to 5 U.S.C. 533(b)(B), there is good cause to waive prior notice and opportunity to provide comment on this action, as notice and comment would be impracticable and contrary to this action for the following reasons. Specifically, the regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments to respond

to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Providing prior notice and an opportunity for public comment on the change in the daily retention limit from three BFT to the default level for the June through August time period would be impracticable. Based on available BFT quotas, fishery performance in recent years, and the availability of BFT on the fishing grounds, responsive adjustment to the General category BFT daily retention limit from three BFT to one fish is warranted to allow fishermen to take advantage of availability of fish and of quota. NMFS could not have proposed this action earlier, as it needed to consider and respond to updated data and information about fishery conditions and this year's landings. If NMFS was to offer a public comment period now, after having appropriately considered that data, it would preclude fishermen from harvesting BFT that are legally available consistent with all of the regulatory criteria, and/or could result in selection of a retention limit inappropriate to the amount of quota available for the period.

Adjustment of the General category retention limit needs to be effective as soon as possible to extend fishing opportunities for fishermen in all geographic areas, and to provide equitable opportunities. Fisheries under the General category daily retention limit are currently underway and thus prior notice would be contrary to the public interest. Delays in decreasing the General category retention limit would adversely affect those General category and HMS Charter/Headboat vessels that would otherwise have an opportunity to harvest BFT if the fishery were to remain open for as long as feasible throughout the remaining time periods. Limited opportunities to harvest the respective quotas may have negative social and economic impacts for U.S. fishermen that depend upon catching the available quota within the time periods designated in the 2006 Consolidated HMS FMP and amendments. NMFS provides notification of retention limit adjustments by publishing the notice in the **Federal Register**, emailing individuals who have subscribed to the Atlantic HMS News electronic newsletter, and updating the information posted on the Atlantic Tunas Information Line and on www.hmspermits.noaa.gov.

For all of the above reasons, the AA finds that pursuant to 5 U.S.C. 553(d), there is also good cause to waive the 30-day delay in effective date.

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

Dated: June 27, 2023.

Jennifer M. Wallace,
*Acting Director, Office of Sustainable
Fisheries, National Marine Fisheries Service.*

[FR Doc. 2023–13966 Filed 6–28–23; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 88, No. 125

Friday, June 30, 2023

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0932; Airspace Docket No. 17–AEA–9]

RIN 2120–AA66

Amendment VOR Federal Airways V–20, V–31, V–33, V–308, and V–433; and Revocation of V–379; in the Vicinity of Nottingham, MD

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA is withdrawing the NPRM published in the **Federal Register** on October 16, 2017, proposing to amend Very High Frequency (VHF) Omnidirectional Range (VOR) Federal airways V–20, V–31, V–33, V–308, and V–433; and revoke V–379; due to the planned decommissioning of the Nottingham, MD (OTT), VOR/Tactical Air Navigation System (VORTAC).
DATES: Effective as of 0901 UTC, June 30, 2023, the proposed rule published October 16, 2017 (82 FR 48011), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Reason for Withdrawal

The FAA published a notice of proposed rulemaking in the **Federal Register** for Docket No. FAA–2017–0932 (82 FR 48011; October 16, 2017). The NPRM proposed to amend VOR Federal airways V–20, V–31, V–33, V–308, and V–433; and revoke V–379; due to the planned decommissioning of the Nottingham, MD, VORTAC (OTT) which provides navigation guidance for portions of the affected airways. Interested parties were invited to

participate in this rulemaking effort by submitting written comments on the proposal. No comments were received. Subsequent to the NPRM, the Nottingham, MD (OTT), VORTAC decommissioning was delayed, and other airway docket actions rendered this proposal unnecessary.

Conclusion

The FAA determined that the NPRM published on October 16, 2017, is unnecessary. Therefore, the FAA withdraws that NPRM.

Issued in Washington, DC, on June 26, 2023.

Brian Konie,

Acting Manager, Airspace Rules and Regulations.

[FR Doc. 2023–13920 Filed 6–29–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0241; Airspace Docket No. 18–AEA–18]

RIN 2120–AA66

Amendment VOR Federal Airways V–260, and V–290; Eastern United States

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA is withdrawing the NPRM published in the **Federal Register** on April 8, 2019, proposing to modify Very High Frequency (VHF) Omnidirectional Range (VOR) Federal airways V–260, and V–290 due to the planned decommissioning of the Rainelle, WV (RNL), VOR.

DATES: Effective as of 0901 UTC, June 30, 2023, the proposed rule published April 8, 2019 (84 FR 13846), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Reason for Withdrawal

The FAA published a notice of proposed rulemaking in the **Federal**

Register for Docket No. FAA–2019–0241 (84 FR 13846; April 8, 2019). The NPRM proposed to amend VOR Federal airways V–260, and V–290 due to the planned decommissioning of the Rainelle, WV (RNL), VOR which provides navigation guidance for portions of the affected airways. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received. Subsequent to the NPRM, the Rainelle, WV (RNL), VOR decommissioning was delayed, and other airway docket actions rendered this proposal unnecessary.

Conclusion

The FAA determined that the NPRM published on April 8, 2019, is unnecessary. Therefore, the FAA withdraws that NPRM.

Issued in Washington, DC, on June 26, 2023.

Brian Konie,

Acting Manager, Airspace Rules and Regulations.

[FR Doc. 2023–13921 Filed 6–29–23; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 18–143; 10–90; Report No. 3196; FR ID 151047]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: Petition for Reconsideration (Petition) has been filed in the Commission's proceeding The Uniendo a Puerto Rico Fund and the Connect USVI Fund.

DATES: Oppositions to the Petition must be filed on or before July 17, 2023. Replies to oppositions must be filed on or before July 10, 2023.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Nathan Eagan of the Wireline Competition Bureau,

Telecommunications Access Policy Division, at (202) 418–0991 or Nathan.Eagan@fcc.gov or Dangkhao Nguyen of the Wireline Competition Bureau, Telecommunications Access Policy Division at (202) 418–7865 or Dangkhao.Nguyen@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3196, released June 21, 2023. The full text of the Petition can be accessed online via the Commission's Electronic Comment Filing System at: <http://apps.fcc.gov/ecfs/>. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

Subject: The Uniendo a Puerto Rico Fund and the Connect USVI Fund (WC Docket Nos. 18–143; 10–90).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–13972 Filed 6–29–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 23–203; FCC 23–52; FRS ID 151775]

All-In Pricing for Cable and Satellite Television Service

AGENCY: Federal Communications Commission

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, The Federal Communications Commission (Commission) propose to require cable operators and direct broadcast satellite providers to clearly and prominently display the total cost of video programming service in promotional materials and on subscribers' bills. Requiring "all-in" pricing is intended to clearly and accurately reflect consumers' subscription payment obligations, eliminate unexpected fees, and allow consumers to comparison shop among competing cable operators and direct broadcast satellite providers as well as alternative programming providers like streaming services. We also seek comment on the effect of imposing such requirements on other types of multichannel video programming distributors and on our authority to do so.

DATES: Submit comments on or before July 31, 2023. Submit reply comments on or before August 29, 2023.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Brendan Murray, Brendan.Murray@fcc.gov, of the Policy Division, Media Bureau, (202) 418–1573.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking*, (NPRM) FCC 23–52, adopted on June 14, 2023, and released on June 20, 2023. These documents will also be available via ECFS (<https://www.fcc.gov/cgb/ecfs/>). (Documents will be available electronically in ASCII, Word, and/or Adobe Acrobat.) To request these documents in accessible formats for people with disabilities, send an email to fcc504@fcc.gov or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis. Access to clear, easy-to-understand, and accurate information about the pricing of video services helps consumers make informed choices and encourages competition in the market. It does so by empowering consumers with information to comparison shop and to find the video programming services that best meets their needs and matches their budget. Consumers who choose a video service based on an advertised monthly price may be surprised by unexpected fees related to the cost of video programming that raise the amount of the bill significantly. These fees, with names like broadcast TV fee, or regional sports programming surcharge, are listed in the fine print as "fees" or "taxes and surcharges," separate from the top line listed service price and can result in a bill that is substantially more than the advertised price. This categorization can be potentially misleading and interpreted as a government-imposed tax or fee, instead of a company-imposed service fee increase. This practice can also make it difficult for consumers to compare the service prices of competing video service providers.

In this Notice of Proposed Rulemaking (NPRM), we propose to enhance pricing transparency by requiring cable operators and direct broadcast satellite (DBS) providers to specify the "all-in" price for service in their promotional materials and on subscribers' bills. This proposal would require cable operators and DBS providers to clearly and prominently display the total cost of video programming service. This all-in pricing

proposal is intended to give consumers a transparent and accurate reflection of their subscription payment obligations and eliminate unexpected fees. It also seeks to provide consumers with the ability to comparison shop among competing cable operators and DBS providers, and to compare programming costs against alternative programming providers, including streaming services. We also seek comment on whether we should consider expanding the requirements of this proceeding to other types of multichannel video programming providers (MVPDs) and on our authority to do so.

Background. Sections 335 and 632 of the Communications Act of 1934, as amended (the Act), authorize the Commission to adopt public interest regulations for DBS and direct the Commission to adopt cable customer service requirements, respectively. In 2019, Congress adopted the Television Viewer Protection Act of 2019 (TVPA), which bolstered the consumer protection provisions of the Act by adding specific consumer protections. The TVPA revised the Act to add section 642, which, among other things, requires greater transparency in subscribers' bills. As it considered this legislation, Congress expressed specific concern that consumers face "unexpected and confusing fees when purchasing video programming," including "fees for broadcast TV," and noted that the practice of charging these fees began in the late 2000s. In 2021, the Media Bureau sought comment on the steps MVPDs have taken to implement the TVPA requirements and on whether consumers found those steps effective in furthering Congress's goal of protecting consumers when purchasing MVPD or broadband service. In response to that PN, Consumer Reports commented that below-the-line fees, "which are solely the creation of the provider (versus regulatory fees that are passed on to the consumer)[,] made up the bulk" of costs that are added to advertised rates and MVPD subscribers' bills. It appears that since adoption of the TVPA, the practice of charging subscribers unexpected "fees" (for example, for broadcast television programming and regional sports programming listed separately from the monthly subscription rate for video programming service) that are actually charges for the video programming service for which the subscriber pays, has continued. Moreover, websites, advertisements, and other promotional materials may advertise a top-line price that does not note prominently the mandatory programming costs that make up the

service until the customer signs up for the service. For example, those materials use a different font size (often in fine print) and separate from the proclaimed monthly subscription fee amounts extra “fees” designated by the provider that consumers will also need to pay for the video programming that they will receive.

Discussion. We believe that the public interest requires that cable operators and DBS providers represent their subscription charges transparently, accurately, and clearly. Accordingly, we propose to require cable operators and DBS providers to provide the “all-in” price for video programming service in their promotional materials and on subscribers’ bills. Below, we seek comment on (i) the specifics of this proposal, (ii) existing Federal, state, and local requirements related to truth-in-billing, (iii) the marketplace practices regarding advertising and billing, and (iv) our legal authority to adopt this proposal. We also seek comment on the costs and benefits of our proposal and the effects that our proposal could have on equity and inclusion.

Proposal Details. We propose to require that cable operators and DBS providers aggregate the cost of the video programming service (that is, any and all amounts that the cable operator or DBS provider charges the consumer for video programming, including for broadcast retransmission consent, regional sports programming, and other programming-related fees) as a prominent single line item on subscribers’ bills and in promotional materials, if they choose to advertise a price in those promotional materials. Section 602 of the Act defines video programming as “programming provided by, or generally considered comparable to programming provided by, a television broadcast station.” We intend for this aggregate amount to include the full amount the cable operator or satellite provider charges (or intends to charge) the customer in exchange for video programming service (such as broadcast television, sports programming, and entertainment programming), but nothing more (that is, no taxes or charges unrelated to video programming). We do not propose to require that cable operators and DBS providers include equipment costs in the “all-in” price listed on promotional materials and bills, as these costs are variable for each subscriber, and some subscribers use their own equipment and therefore do not incur such charges from the provider. We seek comment on this analysis. The goal of this proposal is to provide consumers with the video programming service portion of their

subscription payment for which they are or will be responsible in clear terms. This will allow consumers to make informed choices, including the ability to comparison shop among competing cable operators and DBS providers; compare programming costs against alternative programming providers, including streaming services; and budget for the actual amount that they will need to pay for cable or DBS video service every month, similar to the truth-in-billing rules that the Commission has in place to aid common carrier customers in understanding their bills and making informed choices in the market.

We seek comment on our proposal. Is this proposal sufficient to ensure that subscribers and potential subscribers have accurate information about the cost for video service? To what extent are providers to already advertising an “all-in” price that is inclusive of all video programming-related costs, government-imposed taxes, and fees? Would such materials satisfy our proposal, given that it relates only to charges for video programming? If a provider attempts to attract new subscribers with a total price (which would necessarily be higher than just the price for video programming), does that benefit outweigh the benefits of requiring uniformity for comparison shopping purposes? Are there more consumer-friendly ways that cable operators and DBS providers should be required to provide this information? Is the term “prominent” specific enough to ensure that cable operators and DBS providers present consumers with an easy-to-understand “all-in” subscription price, or do we need to provide more detail about how cable operators and DBS providers must communicate the price for service? For example, should we require cable operators and DBS providers to convey the information in a consistent font size or via some other measurable metric? In cases where the cable operator or DBS provider bundles video programming with other services like broadband internet service, can the cable operator or DBS provider readily identify the amount of the bill that is attributable to video programming, and if not, how should our rulemaking account for those situations? We invite comment, particularly from consumers and local franchising authorities (LFAs), about whether consumers encounter misleading promotions or receive misleading bills, and request that commenters include documents (such as advertisements and bills with redacted personal information) to support their claims.

Subscribers are entitled to clear, concise, and understandable information about the elements that comprise their subscription fees. We also understand that cable operators and DBS providers may wish to (or in some cases are required to under 47 U.S.C. 562) provide their subscribers and potential subscribers with information about how much of their subscription payments are attributable to specific costs of the video programming service, equipment rental, or other items that contribute to the bill. Section 622(c) permits cable operators to identify franchisee fees, public, educational, and governmental access (PEG) fees, and other fees, taxes, assessments, or other charges imposed by the government “as a separate line item on each regular bill of each subscriber.” Section 642(b) states that when an MVPD provides a consumer a bill in an electronic format, that bill shall include an “itemized statement that breaks down the total amount charged for or relating to the provision of the covered service by the amount charged for the provision of the service itself and the amount of all related taxes, administrative fees, equipment fees, or other charges.” The language in our rulemaking is intended to make clear that MVPDs may itemize their bills with even more granularity than the statute requires. We are concerned, however, that some cable operators and DBS providers may currently portray retransmission consent and sports programming costs as separate lines on the bill in such a way as to lead a reasonable consumer to believe that the charge has been mandated by the government, which is a concern that is similar to the concerns that the Commission had with regard to common carriers when it adopted truth-in-billing rules that apply to them. Therefore, consistent with sections 622(c) and 642 of the Act, we propose to explicitly state in our rule that cable operators and DBS providers may complement the prominent aggregate cost line item with an itemized explanation of the elements that compose that aggregate cost, so long as the cable operator or DBS provider portrays the video programming-related costs as part of the all-in price for service. We seek comment on this proposal. Are there consumer benefits to receiving the cost line-item information, which would justify their inclusion on consumer bills? Would a prohibition on separate line items, other than those mandated by section 642 of the Act or permitted under section 622(c) of the Act, better serve the public interest, and if so, could the Commission adopt such

a prohibition consistent with the Act and the First Amendment? Should we require cable operators and DBS providers that choose to itemize portions of their bills to provide a full accounting of how a subscriber's bill is apportioned? For example, should we require cable operators and DBS providers to explain what portion of a bill is attributable to programming costs, or other relevant costs? If so, we seek comment on which categories would best inform consumers about how their payments are apportioned. We invite comment about rules we should consider in order to promote billing and marketing transparency.

Marketplace Practices. We seek comment on industry practices regarding service pricing categorization. Is there a business purpose for characterizing these service rate increases as taxes, fees, or surcharges, and if so, what is this purpose? Are certain sectors in the MVPD marketplace more prone to charging such fees? Aside from line-item fees for broadcast television, sports programming (including regional sports programming), and entertainment programming, are there other video programming-related fees that are being categorized as taxes, fees, and surcharges, instead of included in the price for video service? Have any MVPDs changed the way they bill or promote such fees since the TVPA took effect, and if so, how? Aside from the examples discussed above, are there any other industry practices that are relevant to the analysis of our proposal?

Existing Consumer Protections. We seek comment on whether any existing laws and protections prevent these advertising and billing practices related to charges for video programming that are listed separately on bills as taxes, fees, or surcharges. The Act provides shared authority over cable customer service issues: the Commission sets baseline customer service requirements at the Federal level, and state and local governments tailor more specific customer service regulations based on their communities' needs. Given the bifurcated authority we share with state and local governments, we seek comment on whether any franchising authorities have regulations or franchise agreement terms about these types of billing and advertising practices, and if so, whether they would conflict with our proposal. We seek specific input from franchising authorities about whether any regulations or franchise agreement terms have succeeded in eliminating surprise, below-the-line fees and potentially deceptive advertising, and whether those regulations or terms

would make for appropriate Federal standards for purposes of the practices we are considering here. What other insights can franchising authorities share regarding their experiences in assisting constituents with understanding these billing and/or advertising practices? And have other regulatory bodies addressed this practice? For example, has the Federal Trade Commission investigated any of these advertising and billing practices, and if so, what was the result of that investigation? Have any state attorneys general investigated these practices and found them to violate any state laws? If so, how do such efforts contribute to our efforts in this proceeding?

Legal Authority. We tentatively conclude that sections 335, 632, and 642 of the Act provide ample authority for this proposal. We also tentatively conclude that our proposed rule is consistent with the First Amendment. We seek comment on our analysis below and invite comment on other sources of authority upon which we may rely to support our proposed rule.

We tentatively conclude that section 335 of the Act provides us with authority to adopt our proposed rule as it will apply to direct broadcast satellite (DBS) providers. Section 335(a) provides us with authority to impose on DBS providers "public interest or other requirements for providing video programming." The Commission has not relied on this authority to impose customer service obligations on DBS before, but has recognized that section 335(a) authorizes the adoption of public interest regulations. We tentatively find that the rules we propose here are public interest requirements that fall squarely within our authority under section 335(a). As the Commission recently explained, "Consumer access to clear, easy-to-understand, and accurate information is central to a well-functioning marketplace that encourages competition, innovation, low prices, and high-quality services. The same information empowers consumers to choose services that best meet their needs and match their budgets and ensure that they are not surprised by unexpected charges or service quality that falls short of their expectations." These are some of the same goals that our proposed rule here is intended to accomplish. Although section 335(a) covers requirements for "providing video programming," we do not read that phrase to limit our authority to cover only communications that take place after a DBS provider and consumer enter into a contract. Advertising and promotional materials are often the catalyst for locking

consumers into long-term contracts for the provision of video service. Our proposed rule, as it applies to advertising and other promotional materials, will ensure consumers have accurate and understandable information from the start of their subscriber relationship with the DBS provider, prevent consumer surprise down the road from unexpected charges assessed for "providing video programming," and allow each consumer to have accurate information about the monthly cost in order to choose an MVPD service that best suits his or her needs. Accordingly, we tentatively conclude that we have authority under section 335(a) to apply our proposed rule to DBS providers. We seek comment on this tentative conclusion.

In addition, we seek comment on whether we have authority under section 4(i) of the Act to extend our proposed rule to DBS providers. By doing so, we will ensure uniformity of regulation between and among cable operators (regulated under Title VI and by various state consumer protection laws and local franchising provisions) and DBS providers (under Title III), thereby preventing DBS providers from gaining a competitive advantage over their competitors with potentially misleading marketing materials. We seek comment on this analysis.

Further, we tentatively conclude that section 632 of the Act provides us with authority to adopt our proposed rule as it will apply to cable operators. Section 632(b) provides us authority to establish customer service standards regarding billing practices and other communications with consumers, and we have relied on that authority for decades to regulate in this area. Our mandate under section 632(b) is to adopt customer service requirements regarding, among other enumerated topics, "communications between the cable operator and the subscriber (including standards governing bills and refunds)." Although the statute identifies specific areas that the Commission's customer service standards must cover, section 632 describes these only as the "minimum" standards. Thus, by its terms, section 632(b) gives us broad authority to adopt customer service standards that go beyond those enumerated, including outside the billing context. The legislative history of section 632 provides that "[p]roblems with customer service have been at the heart of complaints about cable television," and Congress believed that "strong mandatory requirements are necessary." Congress expected "the FCC, in

establishing customer service standards to provide standards addressing . . . billing and collection practices; disclosure of all available service tiers, [and] prices (for those tiers and changes in service) . . .” This language from the legislative history—particularly the expectation that the Commission would adopt standards regarding “disclosure of all available service tiers, [and] prices”—suggests that Congress granted the Commission authority over how cable operators disclose their prices to consumers, including prices for services to which consumers may have not yet subscribed. We do not read the reference to “customer service” requirements in section 632(b) to limit the Commission to regulate only post-contract communications; rather, we tentatively find that price information in advertising and other promotional materials is a natural extension of the power Congress expressly delegated to the Commission concerning billing communications between cable operators and subscribers. That is, our proposal seeks to prohibit a cable operator from promoting a potentially misleading price to entice customers to sign up for service and then billing subscribers more than the advertised price. Thus, we tentatively conclude that requiring an “all-in” price for service is the type of “strong mandatory requirement” that Congress contemplated in section 632 and accordingly we have authority under section 632(b) to adopt our proposed rule as applied to cable operators. We seek comment on these tentative conclusions, and whether we should consider expanding the requirements of this proceeding to other types of MVPDs, and on what statutory basis. We also seek comment on the potential competitive effects of applying these requirements to only a subset of video programming providers.

As discussed above, section 642, as added by the TVPA, requires MVPDs to bill subscribers transparently when the MVPD sends an electronic bill, and specifically requires MVPDs to include in their bills “an itemized statement that breaks down the total amount charged for or relating to the provision of the covered service by the amount charged for the provision of the service itself and the amount of all related taxes, administrative fees, equipment fees, or other charges.” We tentatively conclude that our proposal requiring cable operators and DBS providers to provide consumers with the “all-in” price for video programming service meets this statutory directive, at least as it applies to any electronic bill the MVPD sends.

Specifically, our proposal to require cable operators and DBS providers to provide consumers with the total charge for all video programming would ensure that consumers are provided complete and accurate information about the “amount charged for the provision of the service itself,” as Congress intended. We tentatively find that such costs make up the charges for the “provision of the service itself” because broadcast channels, regional sports programming, and other programming track the statutory definition of “video programming” (that is, all are programming provided by, or generally considered comparable to programming provided by, a television broadcast station), and video programming is, by definition, the service that an MVPD makes available for purchase. We tentatively conclude that listing such costs as below-the-line fees potentially results in confusion for consumers about the “amount charged for the provision of the service itself,” because the word “itself” suggests a single charge for the total service rather than one charge for one portion of the service and then a separate charge for other programming provided. This contravenes Congress’s core purpose for enacting the legislation: as noted above, the legislative history of this section indicates that Congress intended to curb MVPDs’ practice of charging “unexpected and confusing fees,” but recent press reports suggest that this practice continues. We observe that the statute further provides for the disclosure of a second group of costs on electronic bills—*i.e.*, “the amount of all related taxes, administrative fees, equipment fees, or other charges.” However, we do not believe that costs related to video programming fall within this category. Such costs are not “taxes,” “administrative fees,” “equipment fees,” or “other charges” because the Act defines video programming as the specific service that customers buy from MVPDs—in other words, the “service itself.” Thus, the terms “taxes,” “administrative fees,” “equipment fees,” or “other charges” cannot reasonably include separate charges for various types of video programming (*e.g.*, amounts paid for retransmission consent rights or rights to transmit regional sports programming or any other programming). We note that section 622(c) permits cable operators to identify, “as a separate line item on each regular bill of each subscriber, . . . [t]he amount of the total bill assessed to satisfy any requirements imposed on the cable operator by the franchise agreement to support public,

educational, or governmental channels or the use of such channels.” 47 U.S.C. 542(c). As noted above, we drafted our proposed rule to be consistent with this rule section by making explicit that cable operators and DBS providers may list discrete costs that make up the “all-in” cost for video programming. Based on this analysis, we tentatively conclude that our proposed rule regarding pricing disclosures is a reasonable construction of these statutory directives and is authorized under the TVPA. Section 642’s silence with respect to the Commission’s rulemaking role does not remove such authority. The courts have previously affirmed the Commission’s authority to promulgate rules implementing a section of the Communications Act even where Congress never explicitly or implicitly delegated power to the Commission to interpret that particular statutory section. We seek comment on these tentative conclusions.

We also tentatively conclude that our proposed rule is consistent with the First Amendment. As the Commission has explained in other contexts where it adopted truth-in-billing, advertising, and labeling rules, “[c]ommercial speech that is misleading is not protected speech and may be prohibited,” and “commercial speech that is only potentially misleading may be restricted if the restrictions directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest.” To what extent is the speech at issue here—portrayal that the cost of video service is a certain amount when the actual amount for the video service is potentially much higher—misleading? Is it categorically misleading such that is not considered protected speech? Or is it only potentially misleading? Is there a credible argument that this practice is not misleading at all?

If a reviewing court were to find that the speech is misleading, the constitutional analysis would end there because the proposed rule simply prevents misleading commercial speech, which is afforded no protection under the First Amendment. However, even if our proposed rule seeks to regulate only potentially misleading speech, regulations involving commercial speech that require a disclosure of factual information (such as the disclosure of the total cost for video programming service that our proposed rule would require) are entitled to more lenient review from courts than regulations that limit speech. That is, under Supreme Court precedent, a speaker’s commercial speech rights are adequately protected as long as

disclosure requirements are reasonably related to the government's interest in preventing deception of consumers. That standard is met here as our proposed rule would simply require cable operators and DBS providers to disclose to consumers in bills and promotional materials an accurate statement of the total cost for video programming service, and the disclosure requirement is reasonably related to the government's interest in preventing deception of consumers. As was the case in *Zauderer*, here, a cable operator's or DBS provider's constitutionally protected interest in *not* providing the required information is "minimal." In addition, the rule does not prevent cable operators and DBS providers from conveying any additional information. We seek comment on this analysis.

Assuming, for the sake of argument, that our proposed rule would be subject to the more stringent test of commercial speech regulation (*i.e.*, intermediate scrutiny), we still believe that the rule passes that three-prong test that the Supreme Court established in *Central Hudson*: first, the government must assert a substantial interest in support of its regulation; second, the government must demonstrate that the restriction on commercial speech directly and materially advances that interest; and third, the regulation must be "narrowly drawn." Our proposed rule passes this test. First, we have a substantial interest in making sure that consumers can identify the full cost of video programming to which they subscribe so that they can understand the price they are being charged for the service as well as make informed purchasing decisions as they consider competing cable and DBS service options. Second, our proposed rule would advance that interest by requiring cable operators and DBS providers to identify the cost for video programming as a single, prominent line-item on consumer bills and promotional materials, which would allow consumers to identify the full cost of video programming. Finally, our proposal is narrowly drawn and proportionate to the substantial interest we aim to promote: the proposed rule would permit cable operators and DBS providers to identify elements that comprise the total charge for video programming and require only that they present information about the total cost for video programming uniformly. We seek comment on this analysis.

Cost/Benefit Analysis. We seek comment on the benefits and costs associated with adopting the proposed rules. In addition to the consumer benefits discussed above, including

promotion of competition, are there also benefits to industry, such as leveling the playing field for cable operators and DBS providers that do offer transparent pricing? We also seek comment on any potential costs that would be imposed on consumers or cable operators and DBS providers if we adopt the proposals contained in this NPRM. Would a truth-in-billing requirement impose undue burdens on small cable operators, as that term is defined by the Small Business Administration? Are there ways to limit any potential compliance burdens on providers, including small cable operators, while still achieving the benefits to consumers discussed above? Comments should be accompanied by specific data and analysis supporting claimed costs and benefits. We seek comment on these issues and any other issues related to the regulation of below-the-line fees and truth-in-billing requirements.

Digital Equity and Inclusion. Finally, the Commission, as part of its continuing effort to advance digital equity for all, including people of color, persons with disabilities, persons who live in rural or Tribal areas, and others who are or have been historically underserved, marginalized, or adversely affected by persistent poverty or inequality, invites comment on any equity-related considerations and benefits (if any) that may be associated with the proposals and issues discussed herein. Specifically, we seek comment on how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well the scope of the Commission's relevant legal authority.

Initial Regulatory Flexibility Act Analysis. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) relating to this NPRM. The IRFA is set forth below.

Paperwork Reduction Act. This NPRM may result in new or revised information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501 through 3520). If the Commission adopts any new or revised information collection requirement, the Commission will publish a notice in the **Federal Register** inviting the public to comment on the requirement, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501–3520). In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might "further reduce the information

collection burden for small business concerns with fewer than 25 employees."

Ex Parte Rules—Permit-But-Disclose. This proceeding shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's ex parte rules. Ex parte presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, ex parte or otherwise, are generally prohibited. Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the ex parte presentation was made, and (2) summarize all data presented and arguments made during the presentation. Memoranda must contain a summary of the substance of the ex parte presentation and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with section 1.1206(b) of the rules. In proceedings governed by section 1.49(f) of the rules or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.*, .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

Filing Requirements—Comments and Replies. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR

1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. 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).

Electronic Filers: Comments may be filed electronically using the internet by accessing the ECFS: <https://fjallfoss.fcc.gov/ecfs2/>.

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. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. 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.

People with Disabilities. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the FCC's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

Availability of Documents. Comments and reply comments will be publicly available online via ECFS.

Initial Regulatory Flexibility Analysis. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) concerning the possible significant economic impact on small entities by the policies and rules proposed in the Notice of Proposed Rulemaking (NPRM). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided on the first page of the NPRM. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

Need for, and Objectives of, the Proposed Rules. Sections 335 and 632 of the Communications Act of 1934, as amended (the Act), authorize the Commission to adopt public interest regulations for direct broadcast satellite (DBS) and direct the Commission to adopt cable customer service requirements, respectively. In 2019, Congress adopted the Television Viewer Protection Act of 2019 (TVPA), which bolstered the consumer protection provisions of the Act by adding specific consumer protections. The TVPA revised the Act to add section 642, which, among other things, requires greater transparency in subscribers' bills. As it considered this legislation, Congress expressed specific concern that consumers face "unexpected and confusing fees when purchasing video programming," including "fees for broadcast TV," and noted that the practice of charging these fees began in the late 2000s. In 2021, the Media Bureau sought comment on the steps multichannel video programming distributors (MVPDs) have taken to implement the TVPA requirements and on whether consumers found those steps effective in furthering Congress's goal of protecting consumers when purchasing MVPD or broadband service. In response to that PN, Consumer Reports commented that below-the-line fees, "which are solely the creation of the provider (versus regulatory fees that are passed on to the consumer)[,] made up the bulk" of costs that are added to advertised rates and MVPD subscribers' bills. It appears that since adoption of the TVPA, the practice of charging subscribers unexpected "fees" (for example, for broadcast television programming and regional sports programming listed separately from the monthly subscription rate for video programming service) that are actually charges for the video programming service for which the subscriber pays, has continued. Moreover, websites, advertisements, and other promotional materials may advertise a top-line price that does not note prominently the mandatory programming costs that make up the service until the customer signs up for service. For example, those materials use a different font size (often in fine print) and separate from the proclaimed monthly subscription fee amounts extra "fees" designated by the provider that consumers will also need to pay for video programming that they will receive.

Some MVPDs charge subscribers an assortment of unexpected fees that are not identified as a cost attributable to the video programming service that they

sell, even though those fees are for parts of that video programming service. This categorization can potentially be misleading and interpreted as a government-imposed tax or fee, instead of a company-imposed service fee increase. This practice can also make it difficult for consumers to compare the service prices of competing video service providers. To make sure that consumers have the information they need to budget for video programming service and compare competitive services,

Legal Basis. The proposed action is authorized pursuant to sections 1, 4(i), 303(v), 335(a), 632(b), and 642 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 303(v), 335(a), 552(b), and 562.

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply—Cable and Other Subscription Programming. The U.S. Census Bureau defines this industry as establishments primarily engaged in operating studios and facilities for the broadcasting of programs on a subscription or fee basis. The broadcast programming is typically narrowcast in nature (e.g., limited format, such as news, sports, education, or youth-oriented). These establishments produce programming in their own facilities or acquire programming from external sources. The programming material is usually delivered to a third party, such as cable systems or direct-to-home satellite systems, for transmission to viewers. The SBA small business size standard for this industry classifies firms with annual receipts less than \$41.5 million as small. Based on U.S. Census Bureau data for 2017, 378 firms operated in this industry during that year. Of that number, 149 firms operated with revenue of less than \$25 million a year and 44 firms operated with revenue of \$25 million or more. Based on this data, the Commission estimates that a majority of firms in this industry are small.

Cable Companies and Systems (Rate Regulation Standard). The Commission has developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a "small cable company" is one serving 400,000 or fewer subscribers, nationwide. Industry data indicate that, of 4,200 cable operators nationwide, all but 9 are small under this size standard. In addition, under the Commission's rules, a "small system" is a cable system serving 15,000 or fewer subscribers. Industry data indicate that, of 4,200 systems nationwide, 3,900 have fewer than 15,000 subscribers, based on the

same records. Thus, under this second size standard, the Commission believes that most cable systems are small.

Cable System Operators (Telecom Act Standard). The Communications Act of 1934, as amended, contains a size standard for a “small cable operator,” which is “a cable operator that, directly or through an affiliate, serves in the aggregate fewer than one percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed \$250,000,000.” For purposes of the Telecom Act Standard, the Commission determined that a cable system operator that serves fewer than 677,000 subscribers, either directly or through affiliates, will meet the definition of a small cable operator based on the cable subscriber count established in a 2001 Public Notice. Based on industry data, only six cable system operators have more than 677,000 subscribers. Accordingly, the Commission estimates that the majority of cable system operators are small under this size standard. We note however, that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed \$250 million. Therefore, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

Direct Broadcast Satellite (DBS) Service. DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic “dish” antenna at the subscriber’s location. DBS is included in the Wired Telecommunications Carriers industry which comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution; and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.

The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 show that 3,054 firms operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Based on this data, the majority of firms in this industry can be considered small under the SBA small business size standard. According to Commission data however, only two entities provide DBS service—DIRECTV (owned by AT&T) and DISH Network, which require a great deal of capital for operation. DIRECTV and DISH Network both exceed the SBA size standard for classification as a small business. Therefore, we must conclude based on internally developed Commission data, in general DBS service is provided only by large firms.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements. The NPRM proposes to require cable operators and DBS providers to state the makeup of consumers’ bills transparently, accurately, and clearly. The NPRM does not propose any new or modified recordkeeping or other compliance requirements.

In assessing the cost of compliance for small entities, at this time the Commission is not in a position to determine whether, if adopted, amending the cable operator customer service obligations will require small entities to hire professionals to comply, and cannot quantify the cost of compliance with any of the potential rule changes that may be adopted. To help the Commission more fully evaluate the cost of compliance, in the NPRM we seek comment on whether a truth-in-billing requirement would impose undue burdens on small entities. We also seek comment on ways to limit any potential compliance burdens on small entities, while still achieving the benefits to consumers of clearer, non-misleading bills and advertisements. Comments should be accompanied by specific data and analysis supporting claimed costs and benefits. In addition, we seek comment on these issues and any other issues related to the regulation of below-the-line fees and truth-in-billing requirements. We expect the comments that we receive from the parties in the proceeding, including cost and benefit analyses, to help the Commission identify and evaluate compliance costs and burdens for small entities that may result from the matters discussed in the NPRM.

Steps Taken to Minimize Significant Economic Impact on Small Entities and Significant Alternatives Considered. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): “(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance, rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.”

The NPRM seeks comment on whether cable operators and DBS providers have changed the way they bill or promote such fees since the TVPA took effect, and if so, how. We ask whether there is a business purpose for characterizing these service rate increases as taxes, fees, or surcharges, and whether certain sectors in the MVPD marketplace more prone to charging such fees. We also ask whether any franchising authorities have regulations or franchise agreement terms about these types of billing and advertising practices, and if so, whether they would conflict with our proposal. Consistent with section 642 of the Act, the NPRM proposes to explicitly state in our rule that cable operators and DBS providers may complement the prominent aggregate cost line item with an itemized explanation of the elements that compose that aggregate cost, so long as the cable operator or DBS provider portrays the video programming-related costs as part of the all-in price for service. There may be consumer benefits to allowing cable operators and DBS providers to provide their subscribers and potential subscribers with information about how much of their subscription payments are attributable to specific elements of the video programming service, equipment rental, or other elements that contribute to the bill.

We considered alternatives to whether our proposal to provide the “all-in” price for service in their promotional materials and on subscribers’ bills is sufficient to ensure that subscribers and potential subscribers have accurate information about the cost for video service. We considered whether there are more consumer-friendly ways that cable operators and DBS providers should be required to provide this information and whether the term “prominent” is specific enough to

ensure that cable operators and DBS providers present consumers with an easy-to-understand “all-in” subscription price, or whether we need to provide more detail about how cable operators and DBS providers must communicate the price for service and seek comment on these matters. We also considered whether, aside from line-item fees for broadcast television, sports programming (including regional sports programming), and entertainment programming, there are other video programming-related fees that are being categorized as taxes, fees, and surcharges, instead of included in the price for video service. We also considered whether there are also benefits to industry, such as leveling the playing field for MVPDs that do offer transparent pricing.

We expect to more fully consider the economic impact and alternatives for small entities following the review of comments and costs and benefits analyses filed in response to the NPRM. Our evaluation of this information will shape the final alternatives we consider, the final conclusion we reach, and any final actions we ultimately take in this proceeding to minimize any significant economic impact that may occur on small entities.

Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rule. None.

It is ordered that, pursuant to the authority found in sections 1, 4(i), 303(v), 335(a), 632(b), and 642 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 303(v), 335(a), 552(b), and 562, this Notice of Proposed Rulemaking is *adopted*. *It is further ordered* that the Commission’s Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 76

Cable television, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene Dortch,
Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 76 as follows:

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

■ 1. The authority citation for part 76 is revised to read as follows:

Authority: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 338, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

■ 2. Add § 76.310 to read as follows:

§ 76.310 Truth in billing and advertising.

Cable operators and direct broadcast satellite (DBS) providers shall aggregate the cost of video programming that they provide as a prominent single line item on subscribers’ bills and in any promotional materials. Cable operators and DBS providers may complement the aggregate line item with an itemized explanation of the elements that compose that single line item.

[FR Doc. 2023–13971 Filed 6–29–23; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 191, 192, and 193

[Docket No. PHMSA–2021–0039]

RIN 2137–AF51

Pipeline Safety: Gas Pipeline Leak Detection and Repair

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: On May 18, 2023, PHMSA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** titled: “Pipeline Safety: Gas Pipeline Leak Detection and Repair.” PHMSA received requests to extend the comment period for stakeholders to have more time to evaluate the NPRM. PHMSA is therefore extending the comment period to August 16, 2023.

DATES: The comment period for the proposed rule published at 88 FR 31890 on May 18, 2023, is extended from July 17, 2023 to August 16, 2023. The agency will, consistent with 49 CFR 190.323, consider late-filed comments to the extent practicable.

ADDRESSES: You may submit comments identified by the docket number PHMSA–2021–0039 by any of the following methods:

E-Gov Web: <https://www.regulations.gov>. This site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the online instructions for submitting comments.

Mail: Docket Management System: U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: U.S. DOT Docket Management System, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1–202–493–2251.

Instructions: Please include the docket number PHMSA–2021–0039 at the beginning of your comments. If you submit your comments by mail, submit two copies. If you wish to receive confirmation that PHMSA has received your comments, include a self-addressed stamped postcard. Internet users may submit comments at <https://www.regulations.gov/>.

Note: Comments are posted without changes or edits to <https://www.regulations.gov>, including any personal information provided. There is a privacy statement published on <https://www.regulations.gov>.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), that can be reviewed at www.dot.gov/privacy.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA, 5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this document contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) mark each page of the original document submission containing CBI as “Confidential”; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Submissions containing CBI should be sent to Sayler Palabrica, Office of Pipeline Safety (PHP–30), Pipeline and Hazardous

Materials Safety Administration (PHMSA), 2nd Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, or by email at sayler.palabrica@dot.gov. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Follow the online instructions for accessing the docket. Alternatively, you may review the documents in person at the street address listed above.

FOR FURTHER INFORMATION CONTACT: Sayler Palabrica, Transportation Specialist, by telephone at 202–744–0825 or by email at sayler.palabrica@dot.gov.

SUPPLEMENTARY INFORMATION:

Background

On May 18, 2023, PHMSA issued a Notice of Proposed Rulemaking titled “Pipeline Safety: Gas Pipeline Leak Detection and Repair”¹ that proposed amendments to the pipeline safety regulations for gas distribution, gas transmission, gas gathering, underground natural gas storage, and liquefied natural gas storage facilities. Since the publication of the NPRM, PHMSA has received comment extension requests from the following entries:

- National Association of Pipeline Safety Representatives
- Gas Piping Technology Committee
- Interstate Natural Gas Association of America, American Fuel and Petrochemical Manufacturers,

American Gas Association, American Petroleum Institute, American Public Gas Association, and the GPA Midstream Association

- Marcellus Shale Coalition
- NiSource Inc.

PHMSA will extend the comment period for the NPRM from July 17, 2023, to August 16, 2023. Consistent with 49 CFR 190.323, PHMSA will consider late-filed comments to the extent practicable.

Issued in Washington, DC, on June 26, 2023, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2023–13900 Filed 6–29–23; 8:45 am]

BILLING CODE 4910–60–P

¹ 88 FR 31890 (May 18, 2023).

Notices

Federal Register

Vol. 88, No. 125

Friday, June 30, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2023–0010]

Notice of Request To Revise an Approved Information Collection: Accreditation of Laboratories, Transactions and Exemptions

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and the Office of Management and Budget (OMB) regulations, FSIS is announcing its intention to request a revision of the approved information collection for the accreditation of laboratories; transactions with official meat and poultry establishments, egg products processing plants, and other firms; and exemptions from requirements of the Federal Meat Inspection Act and the Poultry Products Inspection Act. FSIS has reduced the burden estimate for this collection by 13 hours based on updated information for the accreditation of laboratories. The approval for this information collection will expire on November 30, 2023.

DATES: Submit comments on or before August 29, 2023.

ADDRESSES: FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety

and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2023–0010. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 937–4272 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 937–4272.

SUPPLEMENTARY INFORMATION:

Title: Accreditation of Laboratories, Transactions, and Exemptions.

OMB Number: 0583–0082.

Expiration Date of Approval: November 30, 2023.

Type of Request: Revision of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*) and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled and packaged.

FSIS is requesting a revision of the approved information collection for the accreditation of laboratories; transactions with official meat and poultry establishments, egg products processing plants, and other firms; and exemptions from requirements of the FMIA and the PPIA. FSIS has reduced the burden estimate for this collection by 13 hours based on updated information for the accreditation of

laboratories. The approval for this information collection will expire on November 30, 2023.

FSIS requires accredited non-Federal analytical laboratories to maintain certain records (9 CFR 439.20 & 590.580). The Agency uses this collected information to ensure that non-Federal laboratories act in accordance with FSIS regulations.

The FMIA (21 U.S.C. 642), the PPIA (21 U.S.C. 460(b)), and the EPIA (21 U.S.C. 1040) require establishments, brokers, wholesalers, or otherwise, to keep records that fully and correctly disclose all transactions involved in their businesses related to relevant animal carcasses and parts and egg products.

In addition, FSIS requires establishments to keep records to ensure that meat and poultry products exempted from Agency inspection are not commingled with inspected meat and poultry products (9 CFR 303.1(b)(3) and 381.175).

Finally, FSIS requires retail operations determined to have violated the requirements associated with the retail exemptions in the FMIA and PPIA to keep sales purchase and sales records to ensure future compliance (9 CFR 303.1(d)(3) and 381.10(d)(3)).

FSIS has made the following estimates based upon an information collection assessment:

Respondents: Accredited laboratories, official meat and poultry establishments, egg products processing plants and other firms.

Estimated No. of Respondents: 26,120.

Estimated No. of Annual Responses per Respondent: 122.

Estimated Total Annual Burden on Respondents: 113,458 hours.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 937–4272.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether

the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method 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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status,

income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (e.g., Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720-2600 (voice and TTY); or the Federal Relay Service at (800) 877-8339.

To file a program discrimination complaint, a complainant should complete a Form AD-3027, *USDA Program Discrimination Complaint Form*, which can be obtained online at <https://www.ocio.usda.gov/document/ad-3027>, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by:

(1) *Mail*: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410;

(2) *Fax*: (833) 256-1665 or (202) 690-7442; or

(3) *Email*: program.intake@usda.gov.

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Paul Kiecker,
Administrator.

[FR Doc. 2023-13883 Filed 6-29-23; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS-2023-0013]

Proposed Revisions to the National Handbook of Conservation Practices for the Natural Resources Conservation Service

AGENCY: Natural Resources Conservation Service, U.S. Department of Agriculture.

ACTION: Notice of availability, request for comments.

SUMMARY: The Natural Resources Conservation Service (NRCS) is revising specific conservation practice standards in the National Handbook of Conservation Practices (NHCP). This notice provides an overview of the planned changes and gives the public an opportunity to offer comments on the proposed changes to the specific conservation practice standards.

DATES: We will consider comments that we receive by July 31, 2023.

ADDRESSES: We invite you to submit comments in response to this notice. You may submit your comments through one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and search for Docket ID NRCS-2023-0013. Follow the online instructions for submitting comments.

- *Mail or Hand Delivery:* National Agricultural Engineer, Conservation Engineering Division, NRCS, USDA, 1400 Independence Avenue, South Building, Room 4636, Washington, DC 20250. In your comment, please specify the Docket ID NRCS-2023-0013.

All comments received will be made publicly available on <http://www.regulations.gov>.

Copies of the proposed revised standards are available through <http://www.regulations.gov> by accessing Docket No. NRCS-2023-0013. Alternatively, the proposed revised standards can be downloaded or printed from <https://www.nrcs.usda.gov/getting-assistance/conservation-practices>.

FOR FURTHER INFORMATION CONTACT: Mr. William Reck at (202) 720-4485, or by email at bill.reck@usda.gov. Individuals who require alternative means for communication should contact the U.S. Department of Agriculture (USDA) Target Center at (202) 720-2600 (voice).

SUPPLEMENTARY INFORMATION:

Background

NRCS plans to revise the conservation practice standards in NHCP. This notice provides an overview of the planned changes and gives the public an opportunity to offer comments on the specific conservation practice standards and NRCS's proposed changes.

NRCS State Conservationists who choose to adopt these practices in their states will incorporate these practices into the respective electronic Field Office Technical Guide. These practices may be used in conservation systems that treat highly erodible land (HEL) or on land determined to be wetland. Section 343 of the Federal Agriculture

Improvement and Reform Act of 1996 (Pub. L. 104–127) requires NRCS to make available for public review and comment all proposed revisions to conservation practice standards used to carry out HEL and wetland provisions of the law.

Revisions to NHCP

The extent of the proposed changes varies considerably for each of the conservation practice standards addressed in this notice. To fully understand the proposed changes, individuals are encouraged to compare these changes with each current standard, which can be found at: <https://www.nrcs.usda.gov/resources/guides-and-instructions/conservation-practice-standards>.

NRCS is requesting comments on the following conservation practice standards:

- Fish Raceway or Tank (Code 398);
- Irrigation Pipeline (Code 430);
- Stripcropping (Code 585); and
- Woody Residue Treatment (Code 384).

The following paragraphs highlight some of the proposed changes to each standard.

Fish Raceway or Tank (Code 398): The revised standard expands the practice purposes to include treatment of effluents before release into receiving waters as well as assessment and planning for increased system efficiency to conserve energy use. The revised standard makes clear that it applies to the production of aquatic organisms in general, and not just finfish. We added additional component details for flow-through systems to the “Criteria” section for waste (effluent) management. We removed the species-specific water quality requirements for the two species listed and replaced them with references to land-grant university requirements. We added new content to the “Considerations” section to provide options for recirculating aquaculture system approaches that minimize water use and permit secondary use of wastewater (such as in aquaponics systems). Also, in the “Considerations” section, we added an additional evaluation of the effects of water withdrawal on native aquatic organisms. Finally, we made minor revisions throughout the standard to improve readability, and references were updated based on literature review.

Irrigation Pipeline (Code 430): We made minor rewording edits throughout the standard to improve readability. We added maximum permitted surge for a high-density polyethylene (HDPE) pipe to the “Flexible conduit design” subsection. We added a new subsection

to address protection of pipeline and appurtenances was added to the “Considerations” section. We updated the “Additional Considerations for Economics” subsection to include the collapsible lay flat tubing application, replacement of which is considered operation and maintenance. We updated the “Additional Considerations for Water Quality and Quantity” subsection to include impacts to downstream drinking water and drought mitigation; we also updated references were also updated.

Stripcropping (Code 585): We edited the “Definition,” “Criteria,” and “Considerations” sections of the standard for clarity. We added a reference to the use of the “Implementation Requirement” document to the “Plans and Specifications” section.

Woody Residue Treatment (Code 384): We reduced the practice life span to 1 year and refined the “Purpose” section. We removed two purposes and combined two other purposes. We modified the burning criteria to follow the “Prescribed Burning” (Code 338). We refined the “Considerations,” “plans and Specifications,” and “Operation and Maintenance” sections, and updated references.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotope, American Sign Language, etc.) should contact the responsible agency or USDA’s TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any phone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at the USDA web page on How to File a Program Discrimination Complaint and at any USDA office, or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by (1) mail to U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or (2) email to program.intake@usda.gov.

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Terry Cosby,

Chief, Natural Resources Conservation Service.

[FR Doc. 2023–13929 Filed 6–29–23; 8:45 am]

BILLING CODE 3410–16–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Florida Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Florida Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public meeting via Zoom at 2:00 p.m. ET on Monday, July 17, 2023. The purpose of the meeting is to continue discussing the draft report on voting rights in the state. Members of the public may request a copy of the draft report in advance of the meeting. To do so, please email Liliana Schiller, Support Services Specialist, at lschiller@usccr.gov.

DATES: Monday, July 17, 2023, from 2:00 p.m.–4:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Visual): <https://www.zoomgov.com/j/1613385197>.

Join by Phone (Audio Only): (833) 435–1820 USA Toll-Free; Meeting ID: 161 338 5197.

FOR FURTHER INFORMATION CONTACT: David Mussatt, Designated Federal Officer, at dmussatt@usccr.gov or (312) 353–8311.

SUPPLEMENTARY INFORMATION: This committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email lschiller@usccr.gov at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Mussatt at dmussatt@usccr.gov. Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via www.facadatabase.gov under the Commission on Civil Rights, Florida Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at lschiller@usccr.gov.

Agenda

- I. Welcome & Roll Call
- II. Committee Discussion: Report Draft
- III. Public Comment
- IV. Next Steps
- V. Adjournment

Dated: June 26, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.
[FR Doc. 2023-13888 Filed 6-29-23; 8:45 am]

BILLING CODE 6335-01-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Iowa Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Iowa Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a meeting on Friday, July 21, 2023 at 2:00 p.m.–3:00 p.m. Central time. Committee will hear from a guest speaker and continue to brainstorming potential civil rights topics for their study of the 2021–2025 term.

DATES: The meeting will take place on Friday, July 21, 2023 from 2:00 p.m.–3:00 p.m. Central time.

ADDRESSES:

Join ZoomGov Meeting: <https://www.zoomgov.com/j/1616635286>.

Telephone (Audio Only): Dial 833 435 1820 USA Toll Free; Access code: 161 663 5286.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at dbarreras@usccr.gov or (312) 353-8311

SUPPLEMENTARY INFORMATION: Members of the public can listen to these discussions. Committee meetings are available to the public through the above call in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Corrine Sanders at csanders@usccr.gov. Persons who desire additional information may contact the

Regional Programs Unit at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Pennsylvania Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit at the above email or street address.

Agenda

- I. Welcome from Iowa Advisory Committee Chair
- II. Guest Speaker
- III. Administrative Announcements
- IV. Discuss Civil Rights Topics
- V. Public Comment
- VI. Discuss Next Steps
- VII. Adjournment

Dated: June 27, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.
[FR Doc. 2023-13988 Filed 6-29-23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Georgia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of public meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Georgia Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public meeting via Zoom. The purpose of the meeting is to discuss the post-report activities of the Committee's recent civil rights project on civil asset forfeiture in Georgia.

DATES: Tuesday, August 1, 2023, from 1 p.m.–2 p.m. Eastern Time

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Visual):
<https://www.zoomgov.com/j/1607904311>.

Join by Phone (Audio Only): 1-833-435-1820 USA Toll-Free; Meeting ID: 160 790 4311#.

FOR FURTHER INFORMATION CONTACT: Victoria Moreno, Acting Designated

Federal Officer, at vmoreno@usccr.gov or 1-434-515-0204.

SUPPLEMENTARY INFORMATION: This Committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting “CC” in the meeting platform. To request additional accommodations, please email svillanueva@usccr.gov at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Sarah Villanueva at svillanueva@usccr.gov. Persons who desire additional information may contact the Regional Programs Coordination Unit at 1-434-515-0204.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via www.facadatabase.gov under the Commission on Civil Rights, Georgia Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission’s website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at svillanueva@usccr.gov.

Agenda

- I. Welcome & Roll Call
- II. Approval of Minutes
- III. Announcements and Updates
- IV. Discussion: Post-Report Activities
- V. Next Steps
- VI. Public Comment
- VII. Adjournment

Dated: June 27, 2023.

David Mussatt,
Supervisory Chief, Regional Programs Unit.
[FR Doc. 2023-13982 Filed 6-29-23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-41-2023]

Foreign-Trade Zone 277—Western Maricopa County, Arizona; Application for Expansion (New Magnet Site); Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Greater Maricopa Foreign Trade Zone, Inc., grantee of FTZ 277, requesting authority to expand its zone under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR 400.2(c)) to include a new magnet site in El Mirage, Arizona. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on June 26, 2023.

FTZ 277 was approved by the Board on December 22, 2010 (Board Order 1733, 76 FR 1134, January 7, 2011), reorganized under the ASF on December 16, 2011 (Board Order 1804, 76 FR 80886, December 27, 2011) and expanded on December 23, 2013 (Board Order 1924, 79 FR 2152-2153, January 13, 2014). The zone currently has a service area that includes a portion of Maricopa County and consists of two magnet sites and eight usage-driven sites.

The applicant is now requesting authority to expand its zone to include an additional magnet site: Proposed Site 19 (694 acres)—LogistiCenter at Copperwing located on property south of West Peoria Ave. and north of Northern Parkway, with North El Mirage Rd. as the eastern boundary and Litchfield Rd. as the western boundary in El Mirage, Arizona. The proposed new site is adjacent to the Phoenix Customs and Border Protection port of entry.

In accordance with the FTZ Board’s regulations, Qahira El-Amin of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board’s Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is August 29, 2023. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to September 13, 2023.

A copy of the application will be available for public inspection in the “Online FTZ Information Section” section of the FTZ Board’s website, which is accessible via www.trade.gov/ftz. For further information, contact Qahira El-Amin at Qahira.El-Amin@trade.gov.

Dated: June 26, 2023.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2023-13957 Filed 6-29-23; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Nordwind Airlines, Leningradskaya Str., Building 25, Office 27. 28, Moscow Region, Khimki City, 141402, Russia; Modification of June 15, 2023 Renewal of Temporary Denial Order

Pursuant to Section 766.24 of the Export Administration Regulations, 15 CFR parts 730-774 (2021) (“EAR” or “the Regulations”),¹ I hereby grant the request of the Office of Export Enforcement (“OEE”) to modify the order that I issued on June 15, 2023, renewing the temporary denial order (“TDO”) in this matter (“June 15, 2023 renewal order”).² OEE has requested that the following party be removed from the TDO:

Pegas Touristik, a/k/a Pegas Touristik OOO, 5 building 1 Volokolamsk Highway, Moscow, Russian Federation, 125080, and Yenigöl, Nergiz Sk. No:94/1, Muratpaşa/Antalya, Türkiye, 07230

I. Procedural History

On June 24, 2022, I signed an order denying the export privileges of Nordwind Airlines (“Nordwind”) for a

¹ On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801-4852 (“ECRA”). While section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. app. 2401 *et seq.* (“EAA”), (except for three sections which are inapplicable here), section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (“IEEPA”), and were in effect as of ECRA’s date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

² The June 15, 2023 renewal order was published on June 21, 2023. (88 FR 40202).

period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to section 766.24(a) of the Regulations and was effective upon issuance.³ This temporary denial order was subsequently renewed in accordance with section 766.24(d) of the Regulations.⁴ The renewal order issued on December 20, 2022, and was effective upon issuance.⁵

On May 18, 2023, BIS, through OEE, submitted a written request for renewal of the Nordwind TDO that issued on December 20, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. A copy of the renewal request was sent to Nordwind in accordance with sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO was received. OEE submitted a separate written request under the Regulations that Pegas Touristik be added to the TDO. On June 15, 2023, I issued an order renewing the Nordwind TDO based upon on-going violations of the TDO and the Regulations including the reexport of aircraft subject to the EAR on flights into Russia from Bokhar, Tajikistan, Tehran, Iran, and Osh, Kyrgyzstan, respectively. The June 15 renewal order also added Pegas Touristik as a related person. OEE has since requested that Pegas Touristik be removed from the TDO to allow the opportunity for additional administrative process under part 766 of the Regulations.

Having considered OEE's request, I find that Pegas Touristik should be removed from the TDO to allow the opportunity for additional administrative process under part 766 of the Regulations. The TDO shall remain in full force and effect as to Nordwind.

II. Order

It is therefore ordered:

First, Nordwind Airlines, with an address at Leningradskaya str., building 25, office 27. 28, Moscow region,

Khimki city, 141402, Russia, when acting for or on their behalf, any successors or assigns, agents, or employees, may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of Nordwind any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by Nordwind of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby Nordwind acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from Nordwind of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

D. Obtain from Nordwind in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by Nordwind, or service any item, of whatever origin, that is owned, possessed or controlled by Nordwind if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to Nordwind by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of sections 766.24(e) of the EAR, Nordwind may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202-4022.

In accordance with the provisions of section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Nordwind as provided in section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Nordwind and Pegas Touristik and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect until December 12, 2023, unless renewed in accordance with Section 766.24(d) of the Regulations.

³ The TDO was published in the **Federal Register** on June 29, 2022 (87 FR 38704).

⁴ Section 766.24(d) provides that BIS may seek renewal of a temporary denial order for additional 180-day renewal periods, if it believes that renewal is necessary in the public interest to prevent an imminent violation. Renewal requests are to be made in writing no later than 20 days before the scheduled expiration date of a temporary denial order. Renewal requests may include discussion of any additional or changed circumstances, and may seek appropriate modifications to the order, including the addition of parties as respondents or related persons.

⁵ The December 20, 2022 renewal order was published in the **Federal Register** on December 27, 2022 (87 FR 79725).

Dated: June 27, 2023.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2023–13962 Filed 6–29–23; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Sensors and Instrumentation Technical Advisory Committee; Notice of Partially Closed Meeting—Revised

The Sensors and Instrumentation Technical Advisory Committee (SITAC) will meet on Tuesday, July 18, 2023, at 1:00 p.m., Eastern Daylight Time, in the Herbert C. Hoover Building, Room 3884, 1401 Constitution Avenue NW, Washington, DC (enter through Main Entrance on 14th Street between Constitution and Pennsylvania Avenues). This meeting will be virtual.

The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to sensors and instrumentation equipment and technology. The purpose of the meeting is to have Committee members and U.S. Government representatives mutually review updated technical data and policy-driving information that has been gathered.

Agenda

Open Session

1. Welcome and Introductions.
2. Remarks from the Bureau of Industry and Security Management.
3. Industry Presentations.
4. New Business.

Closed Session

5. Discussion of matters determined to be exempt from the open meeting and public participation requirements found in sections 1009(a)(1) and 1009(a)(3) of the Federal Advisory Committee Act (FACA) (5 U.S.C. 1001–1014). The exemption is authorized by section 1009(d) of the FACA, which permits the closure of advisory committee meetings, or portions thereof, if the head of the agency to which the advisory committee reports determines such meetings may be closed to the public in accordance with subsection (c) of the Government in the Sunshine Act (5 U.S.C. 552b(c)). In this case, the applicable provisions of 5 U.S.C. 552b(c) are subsection 552b(c)(4), which permits closure to protect trade secrets and commercial or financial information that is privileged or confidential, and subsection

552b(c)(9)(B), which permits closure to protect information that would be likely to significantly frustrate implementation of a proposed agency action were it to be disclosed prematurely. The closed session of the meeting will involve committee discussions and guidance regarding U.S. Government strategies and policies.

The open session will be accessible via teleconference. To join the conference, submit inquiries to Ms. Yvette Springer at Yvette.Springer@bis.doc.gov 202–482–2813, no later than July 11, 2023.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 3, 2023, pursuant to 5 U.S.C. 1009(d) of the FACA, that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. 1009(a)(1) and 1009(a)(3). The remaining portions of the meeting will be open to the public.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 3, 2023, pursuant to 5 U.S.C. chapter 10 of the FACA, (5 U.S.C. 1009(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. 1009(a)(1) and 1009(a)(3). The remaining portions of the meeting will be open to the public.

For more information, contact Ms. Springer via email.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2023–13927 Filed 6–29–23; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–053]

Certain Aluminum Foil From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on certain aluminum foil (aluminum foil) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the “Final Results of Sunset Review” section of this notice.

DATES: Applicable June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Erin Kearney, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0167.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2023, Commerce published the notice of initiation of the first sunset review of the AD order on aluminum foil from China,¹ pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).² On March 9, 2023, Commerce received a notice of intent to participate in the sunset review from the Aluminum Association Trade Enforcement Working Group and its individual members, Granges Americas Inc., JW Aluminum Company, Novelis Corporation, and Reynolds Consumer Products, LLC (collectively, the domestic interested parties), within the deadline specified in 19 CFR 351.218(d)(1)(i).³ The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as U.S. producers of aluminum foil, and under section 771(9)(E) of the Act as a business association, a majority of whose members are U.S. producers of the domestic like product.

¹ See *Certain Aluminum Foil from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order*, 83 FR 17362 (April 19, 2018) (Order).

² See *Initiation of Five-Year (Sunset) Reviews*, 88 FR 12915 (March 1, 2023).

³ See Domestic Interested Parties' Letter, “Domestic Interested Parties' Notice of Intent To Participate,” dated March 9, 2023.

On March 31, 2023, the domestic interested parties filed an adequate substantive response within the deadline specified in 19 CFR 351.218(d)(3)(i).⁴ Commerce did not receive a substantive response from any respondent interested party. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order*.

Scope of the Order

The product covered by this *Order* is aluminum foil. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.⁵

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review is provided in the Issues and Decision Memorandum.⁶ A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of dumping, and that the magnitude of the dumping margin likely to prevail would be weighted-average margins of up to 105.80 percent.

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to

judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act.

Dated: June 23, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. History of the *Order*
- V. Legal Framework
- VI. Discussion of the Issues
 1. Likelihood of Continuation or Recurrence of Dumping
 2. Magnitude of Margin of Dumping Likely to Prevail
- VII. Recommendation

[FR Doc. 2023–13954 Filed 6–29–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–970]

Multilayered Wood Flooring From the People's Republic of China: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Final Successor-in-Interest Determination; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Zhejiang Fuerjia Wooden Co., Ltd. (Fuerjia) has not made sales of multilayered wood flooring (wood flooring) from the People's Republic of China (China) at prices below normal value during the period of review (POR) December 1, 2020, through November 30, 2021. In addition, Commerce determines that certain companies had no shipments during the POR or did not establish their eligibility for a separate rate, and that Arte Mundi Group Co., Ltd. (Arte Mundi Group) is the successor-in-interest to Arte Mundi (Shanghai) Aesthetic Home Furnishings Co., Ltd. (Arte Mundi Shanghai).

DATES: Applicable June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Alexis Cherry or Max Goldman, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC, 20230; telephone: 202–482–0607 and 202–482–0224, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of the administrative review on December 28, 2022.¹ For the events that occurred since Commerce published the *Preliminary Results*, see the Issues and Decision Memorandum.² Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). On April 20, 2023, we extended the deadline for these final results to June 23, 2023.³

Scope of the Order⁴

The product covered by the *Order* is wood flooring from China. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the parties' briefs are addressed in the Issues and Decision Memorandum. A list of these issues is attached to this notice.⁵ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to

¹ See *Multilayered Wood Flooring from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review, Preliminary Determination of No Shipments, Preliminary Successor-in-Interest Determination, and Rescission of Review, in Part; 2020–2021*, 87 FR 79859 (December 28, 2022) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Issues and Decision Memorandum: Antidumping Duty Administrative Review of Multilayered Wood Flooring from the People's Republic of China; 2020–2021," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

³ See Memorandum, "Extension of Deadline for Final Results of Antidumping Duty Administrative Review; 2020–2021," dated April 20, 2023.

⁴ See *Multilayered Wood Flooring from the People's Republic of China: Notice of Amended Final Affirmative Determination of Sales at Less than Fair Value and Antidumping Duty Order*, 76 FR 76690 (December 8, 2011), as amended in *Multilayered Wood Flooring from the People's Republic of China: Amended Antidumping and Countervailing Duty Orders*, 77 FR 5484 (February 3, 2012) (collectively, *Order*); see also *Multilayered Wood Flooring from the People's Republic of China: Final Clarification of the Scope of the Antidumping and Countervailing Duty Orders*, 82 FR 27799 (June 19, 2017).

⁵ See Appendix 1.

⁴ See Domestic Interested Parties' Letter, "Domestic Interested Parties' Substantive Response," dated March 31, 2023.

⁵ See Memorandum, "Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Certain Aluminum Foil from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁶ *Id.*

registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Changes From the Preliminary Results

Based on information received since the *Preliminary Results* and for the reasons explained in the Issues and Decision Memorandum, we are revising the surrogate value for labor.⁶

Final Determination of No Shipments

In the *Preliminary Results*, Commerce determined that certain companies did not have shipments of subject merchandise during the POR.⁷ These companies are listed in Appendix II of this notice. As we received no information to contradict our preliminary determination with respect to those companies, we continue to find that they made no shipments of subject merchandise to the United States during the POR. Accordingly, we will issue appropriate instructions that are consistent with our “automatic assessment” clarification for all of the companies listed in Appendix II.⁸

Final Results of Successor-in-Interest Analysis

In the *Preliminary Results*, Commerce determined that Arte Mundi Group is the successor-in-interest to Arte Mundi Shanghai.⁹ No party commented on this issue, and we have not received any information to contradict our preliminary finding. Therefore, we continue to find that Arte Mundi Group is the successor-in-interest to Arte Mundi Shanghai.

Separate Rates

We determine that Fuerjia and four additional companies that were not selected for individual review demonstrated their eligibility for separate rates. These companies are listed in the table in the “Final Results of Administrative Review” section below. We continue to find that Metropolitan Hardwood Floors, Inc.¹⁰ and five other companies are not eligible for a separate rate. These

companies are listed in Appendix III of this notice.

Rate for Non-Examined Separate Rate Respondents

The statute and our regulations do not address the establishment of a rate to be assigned to respondents not selected for individual examination when we limit our examination of companies subject to the administrative review pursuant to section 777A(c)(2)(B) of the Act. Generally, we look to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents not individually examined in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally “an amount equal to the weighted average of the estimated weighted average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely {on the basis of facts available}.” Accordingly, Commerce’s usual practice in determining the rate for separate-rate respondents not selected for individual examination, has been to average the weighted-average dumping margins of the selected companies, excluding rates that are zero, *de minimis*, or based entirely on facts available.¹¹ However, when the weighted-average dumping margins established for all individually investigated respondents are zero, *de minimis*, or based entirely on facts available, section 735(c)(5)(B) of the Act permits Commerce to “use any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted-average dumping margins determined for the exporters and producers individually investigated.”¹²

For the final results of this review, we continue to determine the estimated dumping margin for Fuerjia, the sole cooperative mandatory respondent in this review, to be zero percent. Thus, consistent with the *Preliminary Results*, we are assigning this rate to the non-

examined respondents which qualify for a separate rate in this review.¹³

The China-Wide Entity

Aside from the companies for which we made a final no-shipment determination, Commerce considers all other companies for which a review was requested, and which did not demonstrate separate rate eligibility, to be part of the China-wide entity.¹⁴

Final Results of Administrative Review

For the companies subject to this administrative review which established their eligibility for a separate rate, Commerce determines that the following weighted-average dumping margins exist for the period December 1, 2020, through November 30, 2021:

Exporter	Weighted-average dumping margin (percent)
Zhejiang Fuerjia Wooden Co., Ltd	0.00
Dalian Penghong Floor Products Co., Ltd./Dalian Shumaik	
Floor Manufacturing Co., Ltd ..	0.00
Huzhou Fulinmen Imp. & Exp. Co., Ltd	0.00
Jiangsu Guyu International Trading Co., Ltd	0.00
Zhejiang Dadongwu Greenhome Wood Co., Ltd	0.00

Disclosure

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with these final results of review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

⁶ See Issues and Decision Memorandum at “Changes to the Preliminary Results” and Comment 3.

⁷ See *Preliminary Results* PDM at 6–8.

⁸ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011) (*Assessment Notice*); see also “Assessment Rates” section, below.

⁹ See *Preliminary Results* PDM at 8–11.

¹⁰ See Issues and Decision Memorandum at Comment 2.

¹¹ See *Longkou Haimeng Mach. Co. v. United States*, 581 F. Supp. 2d 1344, 1357–60 (CIT 2008) (affirming Commerce’s determination to assign a 4.22 percent dumping margin to the separate-rate respondents in a segment where the three mandatory respondents received dumping margins of 4.22 percent, 0.03 percent, and zero percent, respectively); see also *Certain Kitchen Appliance Shelving and Racks from the People’s Republic of China: Final Determination of Sales at Less Than Fair Value*, 74 FR 36656, 36660 (July 24, 2009).

¹² See *Albemarle Corp. v. United States*, 821 F.3d 1345 (Fed. Cir. 2016).

¹³ See *Preliminary Results* PDM at 15–16; see also Issues and Decision Memorandum at Comment 2; and section 735(c)(5)(B) of the Act.

¹⁴ See Appendix III.

For Fuerjia and the respondents which were not selected for individual examination in this administrative review and which qualified for a separate rate, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. For entries that were not reported in the U.S. sales databases submitted by Fuerjia, and for the companies that did not qualify for a separate rate in the administrative review, Commerce will instruct CBP to liquidate such entries at the China-wide rate (*i.e.*, 85.13 percent).¹⁵

Consistent with Commerce's assessment practice in non-market economy cases, for the companies which Commerce determined had no shipments of the subject merchandise, any suspended entries made under those exporters' case numbers (*i.e.*, at the exporters' rates) will be liquidated at the China-wide rate.¹⁶

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of these final results for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) for companies which were found eligible for a separate rate in this review, the cash deposit rate will be zero; (2) for previously investigated or reviewed Chinese and non-Chinese exporters that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR

351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: June 23, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Changes to the *Preliminary Results*
- V. Discussion of the Issues
 - Comment 1: Whether To Apply Adverse Facts Available (AFA) to Fuerjia
 - Comment 2: Whether To Find Metropolitan Eligible for a Separate Rate
 - Comment 3: Whether To Select Malaysia or Romania as the Primary Surrogate Country
 - Comment 4: Whether To Revise the Surrogate Value (SV) for Plywood
 - Comment 5: Whether To Use Multiple Financial Statements in the Surrogate Financial Ratios
- VI. Recommendation

Appendix II

No Shipments

Anhui Longhua Bamboo Product Co., Ltd.
 Arte Mundi Group Co., Ltd. (successor-in-interest to Arte Mundi (Shanghai)
 Aesthetic Home Furnishings Co., Ltd.)
 Benxi Flooring Factory (General Partnership)
 Benxi Wood Company

Dalian Deerfu Wooden Product Co., Ltd.
 Dalian Jiahong Wood Industry Co., Ltd.
 Dalian Shengyu Science And Technology Development Co., Ltd.
 Dongtai Fuan Universal Dynamics, LLC
 Dun Hua Sen Tai Wood Co., Ltd.
 Dunhua City Dexin Wood Industry Co., Ltd.
 Dunhua City Hongyuan Wood Industry Co., Ltd.
 Dunhua Shengda Wood Industry Co., Ltd.
 HaiLin LinJing Wooden Products Co., Ltd.
 Hunchun Xingjia Wooden Flooring Inc.
 Huzhou Chenghang Wood Co., Ltd.
 Huzhou Sunergy World Trade Co., Ltd.
 Jiangsu Keri Wood Co., Ltd.
 Jiangsu Mingle Flooring Co., Ltd.
 Jiangsu Simba Flooring Co., Ltd.
 Jiangsu Yuhui International Trade Co., Ltd.
 Jiashan On-Line Lumber Co., Ltd.
 Kingman Wood Industry Co., Ltd.
 Linyi Anying Wood Co., Ltd.
 Linyi Youyou Wood Co., Ltd.
 Muchsee Wood (Chuzhou) Co., Ltd.
 Pingte Timber Manufacturing (Zhejiang) Co., Ltd.
 Power Dekor Group Co., Ltd.
 Sino-Maple (Jiangsu) Co., Ltd.
 Suzhou Dongda Wood Co., Ltd.
 Tongxiang Jisheng Import and Export Co., Ltd.
 Yekalon Industry Inc.
 Zhejiang Longsen Lumbering Co., Ltd.
 Zhejiang Shiyu Timber Co., Ltd.
 Zhejiang Shuimojiangnan New Material Technology Co., Ltd.

Appendix III

China-Wide Entity

Jiashan HuiJiaLe Decoration Material Co., Ltd.
 Jiaying Hengtong Wood Co., Ltd.
 Lauzon Distinctive Hardwood Flooring, Inc.
 Metropolitan Hardwood Floors, Inc.
 Yihua Lifestyle Technology Co., Ltd.
 (successor-in-interest to Guangdong Yihua Timber Industry Co., Ltd.)
 Yingyi-Nature (Kunshan) Wood Industry Co., Ltd.

[FR Doc. 2023-13955 Filed 6-29-23; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-580-876]

Welded Line Pipe From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that certain producers/exporters subject to this administrative review made sales of subject merchandise at less than normal value (NV) during the period of review (POR) December 1, 2020, through November 30, 2021.

¹⁵ See *Multilayered Wood Flooring from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2016–2017*, 84 FR 38002, 38003 (August 5, 2019).

¹⁶ For a full discussion of this practice, see *Assessment Notice*.

DATES: Applicable June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Adam Simons, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-6172.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2022, Commerce published the *Preliminary Results* of the 2020–2021 administrative review of the antidumping duty order on welded line pipe (WLP) from the republic of Korea (Korea) and invited interested parties to comment.¹ This review covers 31 producers/exporters of the subject merchandise. Commerce selected two companies, NEXTEEL Co., Ltd. (NEXTEEL) and SeAH Steel Corporation (SeAH), for individual examination.² The producers/exporters not selected for individual examination are listed in Appendix II.

On February 6, 2023, we received case briefs from the Domestic Interested Parties,³ NEXTEEL, and SeAH.⁴ On February 14, 2023, we received rebuttal briefs from Domestic Interested Parties, NEXTEEL, and SeAH, as well as a letter in-lieu-of a rebuttal brief from Hyundai Steel Company.⁵ On April 6, 2023, we postponed the final results to no later than June 27, 2023.⁶ For a complete description of the events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.⁷

¹ See *Welded Line Pipe from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2020–2021*, 87 FR 80156 (December 29, 2022) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, “Respondent Selection,” dated February 22, 2022.

³ The Domestic Interested Parties are American Cast Iron Pipe Company, Dura-Bond Industries, Stupp Corporation, Welspun Global Trade LLC, and Axis Pipe & Tube.

⁴ See Domestic Interested Parties’ Letter, “Case Brief,” dated February 6, 2023; NEXTEEL’s Letter, “NEXTEEL’s Case Brief,” dated February 6, 2023; and SeAH’s Letter, “Case Brief of SeAH Steel Corporation,” dated February 6, 2023.

⁵ See Domestic Interested Parties’ Letter, “Rebuttal Brief,” dated February 14, 2023 (Domestic Interested Parties’ Rebuttal Brief); NEXTEEL’s Letter, “NEXTEEL’s Rebuttal Brief,” dated February 14, 2023 (NEXTEEL’s Rebuttal Brief); SeAH’s Letter, “Rebuttal Brief of SeAH Steel Corporation,” dated February 14, 2023 (SeAH’s Rebuttal Brief); and Hyundai Steel Company’s Letter, “Letter in Support of Mandatory Respondents’ Case and Rebuttal Briefs,” dated February 14, 2023.

⁶ See Memorandum, “Extension of Deadline for Final Results of 2020–2021 Antidumping Duty Administrative Review,” dated April 6, 2023.

⁷ See Memorandum, “Issues and Decision Memorandum for the Final Results of the 2020–2021 Administrative Review of the Antidumping

Scope of the Order⁸

The merchandise subject to the *Order* is welded line pipe.⁹ The product is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) item numbers: 7305.11.1030, 7305.11.1060, 7305.11.5000, 7305.12.1030, 7305.12.1060, 7305.12.5000, 7305.19.1030, 7305.19.5000, 7306.19.1010, 7306.19.1050, 7306.19.5110, and 7306.19.5150. Although the HTSUS numbers are provided for convenience and for customs purposes, the written product description remains dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in Appendix I to this notice and addressed in the Issues and Decision Memorandum. Interested parties can find a complete discussion of these issues and the corresponding recommendations in this public memorandum, which is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results*, we made certain changes to the calculation of the preliminary weighted-average dumping margins for NEXTEEL and SeAH.¹⁰

Determination of No Shipments

As noted in the *Preliminary Results*, we received a no shipment claim from HiSteel Co., Ltd. (HiSteel) and preliminarily determined that HiSteel had no shipments during the POR.¹¹ We received no comments from interested parties with respect to this claim. Therefore, because the record indicates that HiSteel had no entries of subject merchandise to the United States during

Duty Order on Welded Line Pipe from Korea,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁸ See *Welded Line Pipe from the Republic of Korea and the Republic of Turkey: Antidumping Duty Orders*, 80 FR 75056, 75057 (December 1, 2015) (*Order*).

⁹ For a complete description of the scope of the order, see *Preliminary Results* PDM at 3.

¹⁰ For a full description of changes, see Issues and Decision Memorandum.

¹¹ See *Preliminary Results*.

the POR, we continue to find that HiSteel had no shipments during the POR.

Rates for Companies Not Selected for Individual Examination

Generally, Commerce looks to section 735(c)(5) of the Tariff Act of 1930, as amended (the Act), which provides instructions for calculating the all-others rate in an investigation, for guidance for calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally “an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.”

In this review, we calculated a weighted-average dumping margin of 2.38 percent for NEXTEEL and a weighted-average dumping margin of 4.23 percent for SeAH. With two respondents under individual examination, Commerce normally calculates: (A) a weighted-average of the estimated dumping rates calculated for the examined respondents; (B) a simple average of the estimated dumping rates calculated for the examined respondents; and (C) a weighted-average of the estimated dumping rates calculated for the examined respondents using each company’s publicly-ranged U.S. sale values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters.¹²

Consistent with our practice, we have determined that 3.27 percent, which is the weighted average of NEXTEEL and SeAH’s margins based on publicly ranged data, will be assigned to the non-examined companies under section 735(c)(5)(A) of the Act.¹³ These companies are listed in Appendix II.

Final Results of the Review

As a result of this review, we determine the following weighted-average dumping margins for the period

¹² See, e.g., *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53663 (September 1, 2010).

¹³ For a complete analysis of the data, see Memorandum, “Calculation of the Cash Deposit Rate for Non-Selected Companies,” dated concurrently with this notice.

December 1, 2020, through November 30, 2021:

Producer or exporter	Weighted-average dumping margin (percent)
NEXTEEL Co., Ltd	2.38
SeAH Steel Corporation	4.23
Companies Not Selected for Individual Review ¹⁴	3.27

Disclosure of Calculations

We intend to disclose the calculations performed for NEXTEEL and SeAH in connection with these final results to interested parties within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), NEXTEEL reported the entered value of its U.S. sales such that we calculated importer-specific ad valorem duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. SeAH did not report the actual entered value for all of its U.S. sales; in such instances, we calculated importer-specific per-unit duty assessment rates by aggregating the total amount of antidumping duties calculated for the examined sales and dividing this amount by the total quantity of those sales. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies not selected for individual review, we used an assessment rate based on the weighted average of the cash deposit rates calculated for NEXTEEL and SeAH. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for the future deposits of estimated duties where applicable.¹⁵

Commerce's "automatic assessment" practice will apply to entries of subject merchandise during the POR produced by NEXTEEL or SeAH for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.*, a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies covered in this review will be equal to the weighted-average dumping margin that is established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the cash deposit rate established for the most recently completed segment for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 4.38 percent, the all-others rate established in the LTFV investigation.¹⁶ These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 26, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Margin Calculations
- IV. Discussion of the Issues
 - Comment 1: Treatment of NEXTEEL's Non-Prime Products
 - Comment 2: NEXTEEL's Quarterly Cost
 - Comment 3: NEXTEEL's Suspended Production Lines
 - Comment 4: NEXTEEL's Obsolete Hot Rolled Steel Coil
 - Comment 5: Treatment of Cost of Goods Sold Assigned to SeAH's Headquarters
 - Comment 6: SeAH's Scrap Offset
 - Comment 7: SeAH's General and Administrative Expenses
 - Comment 8: SeAH's Interest Expense Ratio
 - Comment 9: Reconciliation of State Pipe & Supply, Inc.'s Cost of Further Manufacturing
 - Comment 10: State Pipe's COGS Accounts
 - Comment 11: State Pipe's G&A Expenses
 - Comment 12: State Pipe's Loan Forgiveness
 - Comment 13: Whether SeAH's Reported Movement Expenses Should Be Deducted From its Home Market Price

¹⁴ See Appendix II for a full list of these companies.

¹⁵ See section 751(a)(2)(C) of the Act.

¹⁶ See *Order*.

Comment 14: Whether Commerce Should Use SeAH's Reported Surrogate Costs
 Comment 15: SeAH's Constructed Export Price Offset
 Comment 16: Differential Pricing Methodology
 Comment 17: SeAH's Assessment Rates
 V. Recommendation

Appendix II

List of Companies Not Selected for Individual Review Receiving the Review-Specific Rate

1. AJU BESTEEL Co., Ltd.
2. BDP International, Inc.
3. Daewoo International Corporation
4. Dong Yang Steel Pipe
5. Dongbu Incheon Steel Co.
6. Dongbu Steel Co., Ltd.
7. Dongkuk Steel Mill
8. EEW Korea Co., Ltd.
9. Husteel Co., Ltd.
10. Hyundai RB Co. Ltd.
11. Hyundai Steel Company/Hyundai HYSCO
12. Kelly Pipe Co., LLC
13. Keonwoo Metals Co., Ltd.
14. Kolon Global Corp.
15. Korea Cast Iron Pipe Ind. Co., Ltd.
16. Kurvers Piping Italy S.R.L.
17. Miju Steel MFG Co., Ltd.
18. MSTEEL Co., Ltd.
19. Poongsan Valinox (Valtimet Division)
20. POSCO
21. POSCO Daewoo
22. R&R Trading Co. Ltd.
23. Sam Kang M&T Co., Ltd.
24. Sin Sung Metal Co., Ltd.
25. SK Networks
26. Soon-Hong Trading Company
27. Steel Flower Co., Ltd.
28. TGS Pipe
29. Tokyo Engineering Korea Ltd.

[FR Doc. 2023-13965 Filed 6-29-23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C-533-884]

Glycine From India: Preliminary Results of Countervailing Duty Administrative Review and Rescission, in Part; 2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that countervailable subsidies are being provided to producers and exporters of glycine from India during the period of review, January 1, 2021, through December 31, 2021. Interested parties are invited to comment on these preliminary results.

DATES: Applicable June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Scarlet Jaldin or Harrison Tanchuck,

AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-4275 or (202) 482-7421, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 21, 2019, Commerce published the countervailing duty order on glycine from India.¹ On June 3, 2022, Commerce published in the **Federal Register** a notice of initiation of an administrative review of the *Order*.² Between June 27 and 30, 2022, Commerce received timely requests for administrative reviews of several companies from various interested parties, in accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.213(b)(1).³ On August 9, 2022, based on these timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), Commerce published in the **Federal Register** a notice of initiation of the *Order* covering five producers/exporters.⁴ On September 23, 2022, Paras withdrew its request for review of itself.⁵ On November 7, 2022, Avid timely withdrew its request for review of itself⁶ and the petitioner timely withdrew its request for an administrative review of Avid.⁷ On November 9, 2022, Commerce notified interested parties of its intent to rescind the review, in part, with respect to Avid.⁸ On February 27, 2023, Commerce extended the time period for issuing

these preliminary results by 119 days, in accordance with section 751(a)(3)(A) of the Act, to no later than June 29, 2023.⁹

For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.¹⁰ A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received timely-filed letters withdrawing the requests from Avid, Paras, and the petitioner, pursuant to 19 CFR 351.213(d)(1).¹¹ Because the withdrawal letters were timely filed, and no other party requested a review of the companies listed in the withdrawal letters, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to Avid and Paras.

Scope of the Order

The merchandise covered by the *Order* is glycine from India. For a complete description of the scope of the *Order*, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found to be countervailable, we preliminarily find that there is a subsidy, *i.e.*, a financial contribution

⁹ See Memorandum, "Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review," dated February 27, 2023.

¹⁰ See Memorandum, "Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Glycine from India; 2021," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

¹¹ See Avid Withdrawal of Review Request; see also Petitioner Withdrawal of Review Request; and Paras Withdrawal of Review Request.

¹ See *Glycine from India and the People's Republic of China: Countervailing Duty Orders*, 84 FR 29173 (June 21, 2019) (*Order*).

² See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 87 FR 48459, 48463 (August 9, 2022) (*Initiation Notice*).

³ See Kumar Industries, India's (Kumar) Letter, "Request for Administrative Review of Countervailing Duty," dated June 27, 2022; see also Paras Intermediates Private Limited's (Paras) Letter, "Request for Countervailing Duty Administrative Review," dated June 28, 2022; Avid Organics Private Limited's (Avid) Letter, "Request for Countervailing Duty Administrative Review," dated June 28, 2022; and GEO Specialty Chemicals, Inc.'s (the petitioner) Letter, "Request for Administrative Review," dated June 30, 2022.

⁴ See *Initiation Notice*, 87 FR at 48463.

⁵ See Paras' Letter, "Withdrawal of Review Request for Countervailing Duty Administrative Review," dated September 23, 2022 (Paras Withdrawal of Review Request).

⁶ See Avid's Letter, "Withdrawal of Review Request for Countervailing Duty Administrative Review," dated November 7, 2022 (Avid Withdrawal of Review Request).

⁷ See Petitioner's Letter, "Partial Withdrawal of Request for Administrative Review," dated November 7, 2022 (Petitioner Withdrawal of Review Request).

⁸ See Memorandum, "Notice of Intent to Rescind Review, in Part," dated November 9, 2022.

that gives rise to a benefit to the recipient, and that the subsidy is specific.¹² For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum.

Companies Not Selected for Individual Review

There are two companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross-owned with the mandatory respondent (Kumar): Rudraa International; and Rexusize Rasayan Industries. The Act and Commerce's regulations do not directly address the subsidy rate to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation.

Section 777A(e)(2) of the Act provides that "the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}." Section 705(c)(5)(A) of the Act articulates a preference that we are not to calculate an all-others rate using rates which are zero, *de minimis*, or based entirely on facts available. Accordingly, Commerce's usual practice in determining the rate for non-examined respondents has been to weight-average the net subsidy rates for the selected companies, excluding rates that are zero, *de minimis*, or based entirely on facts available.¹³

For these preliminary results, Kumar is the sole mandatory respondent with a calculated rate above *de minimis* that is not based entirely on facts available. Therefore, we are preliminarily assigning Kumar's net countervailable subsidy rate to the two remaining, non-examined companies, for which an individual rate was not calculated: Rudraa International; and Rexusize Rasayan Industries.

Preliminary Results of Review

For the period January 1, 2021, through December 31, 2021, we preliminarily find that the following net subsidy rates exist:

Company	Subsidy rate (percent <i>ad valorem</i>)
Kumar Industries, India ¹⁴	6.03
Rudraa International	6.03
Rexusize Rasayan Industries	6.03

Assessment Rate

Consistent with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. For companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption during period January 1, 2021, through December 31, 2021, in accordance with 19 CFR 351.212(c)(1)(i). For the companies remaining in the review, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

Pursuant to section 751(a)(1) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respondents listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, Commerce will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the

all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Disclosure

Commerce intends to disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results, in accordance with 19 CFR 351.224(b).

Public Comment

Case briefs or other written documents may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of this **Federal Register** notice. Rebuttal briefs, limited to issues raised in case briefs, may be submitted within seven days after the time limit for filing case briefs.¹⁵ Pursuant to 19 CFR 351.309(c)(2) and 19 CFR 351.309(d)(2), parties which submit arguments are requested to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.¹⁶ Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.¹⁷

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must do so within 30 days of publication of this notice by submitting a written request to the Assistant Secretary for Enforcement and Compliance.¹⁸ Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether a participant is a foreign national; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date and time of the hearing two days before the scheduled date.

Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and that electronically filed documents must be

¹² See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

¹³ See, e.g., *Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review*, 75 FR 37387 (June 29, 2010).

¹⁴ In this review, Commerce found the following company to be cross-owned with Kumar: Advance Chemical Corporation. See Preliminary Decision Memorandum; see also Memorandum, "Preliminary Results Calculation Memorandum for Kumar Industries, India," dated concurrently with this notice.

¹⁵ See 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1); see also 19 CFR 351.303 (for general filing requirements).

¹⁶ See 19 CFR 351.309(c)(2) and 351.309(d)(2).

¹⁷ See *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19; Extension of Effective Period*, 85 FR 41363 (July 10, 2020).

¹⁸ See 19 CFR 351.310(c).

received successfully in their entirety by 5 p.m. Eastern Time on the due date.

Unless the deadline is extended, Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Interested Parties

These preliminary results and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 19 CFR 351.221(b)(4).

Dated: June 26, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Review
- IV. Scope of the Order
- V. Rescission of Administrative Review, In Part
- VI. Rate for Non-Examined Companies
- VII. Subsidies Valuation Information
- VIII. Benchmarks and Interest Rates
- IX. Analysis of Programs
- X. Recommendation

[FR Doc. 2023–13964 Filed 6–29–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–916, C–508–815, C–580–917]

Brass Rod From India, Israel, and the Republic of Korea: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Dusten Hom (India), Zachary Shaykin (Israel), and Jacob Saude (the Republic of Korea), AD/CVD Operations, Offices I, IV, and VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5075, (202) 482–2638, or (202) 482–0981, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 17, 2023, the U.S. Department of Commerce (Commerce) initiated countervailing duty (CVD) investigations of imports of brass rod from India, Israel, and the Republic of Korea (Korea).¹ Currently, the preliminary determinations are due no later than July 21, 2023.

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act) requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On June 22, 2023, the petitioners submitted a timely request that Commerce postpone the preliminary determinations in these investigations.² The petitioners stated that additional time is needed to collect the necessary information for the preliminary determinations.³

In accordance with 19 CFR 351.205(e), the petitioners have stated the reasons for requesting a postponement of the preliminary determinations, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations to no later than 130 days after the date on which these investigations were initiated, *i.e.*,

¹ See *Brass Rod From India, Israel, and the Republic of Korea: Initiation of Countervailing Duty Investigations*, 88 FR 33566 (May 24, 2023).

² See Petitioners' Letters, "Request to Extend CVD Preliminary Determination," dated June 22, 2023. The petitioners are Mueller Brass Co. and Wieland Chase LLC, collectively, the American Brass Rod Fair Trade Coalition.

³ *Id.*

September 25, 2023.⁴ Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: June 26, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2023–13956 Filed 6–29–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–895]

Low Melt Polyester Staple Fiber From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that the sole producer/exporter subject to this administrative review made sales of subject merchandise at less than normal value (NV) during the period of review (POR) August 1, 2021, through July 31, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable June 30, 2023.

FOR FURTHER INFORMATION CONTACT:

Alice Maldonado or Andrew Hart, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4682 or (202) 482–1058, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 11, 2022, based on a timely request for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review on low melt polyester staple fiber (low melt

⁴ The deadline for the preliminary determinations falls on Sunday, September 24, 2023. Commerce's practice dictates that where a deadline falls on a weekend or Federal holiday, the appropriate deadline is the next business day (in this instance, Monday, September 25, 2023). See *Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended*, 70 FR 24533 (May 10, 2005).

PSF) from the Republic of Korea (Korea).¹ The review covers one producer/exporter of the subject merchandise, Toray Advanced Materials Korea, Inc. (TAK).

On April 26, 2023, Commerce extended the deadline for the preliminary results of this administrative review until June 30, 2023.² For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.³

Scope of the Order⁴

The merchandise subject to the *Order* is synthetic staple fibers, not carded or combed, specifically bi-component polyester fibers having a polyester fiber component that melts at a lower temperature than the other polyester fiber component (low melt PSF). For a complete description of the scope of the *Order*, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Preliminary Results of Review

As a result of this review, we preliminarily determine that the following weighted-average dumping margin exists for TAK for the period August 1, 2021, through July 31, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Toray Advanced Materials Korea, Inc	3.61

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice.⁵ Case briefs or other written comments may be submitted to Commerce no later than 30 days after the date of publication of this notice.⁶ Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the time limit for filing case briefs.⁷ Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.⁸ Case and rebuttal briefs should be filed using ACCESS.⁹ Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.¹⁰

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically via ACCESS within 30 days after the date of publication of this notice.¹¹ Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.¹² Parties should

confirm by telephone the date and time of the hearing two days before the scheduled date. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless otherwise extended.¹³

Assessment Rates

Upon completion of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries.¹⁴ Pursuant to 19 CFR 351.212(b)(1), if TAK's weighted-average dumping margin is not zero or *de minimis* (i.e., less than 0.5 percent) in the final results of this review, we will calculate importer-specific assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales.¹⁵ Where TAK did not report entered value, we will calculate the entered value in order to calculate the assessment rate. If TAK's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate entries without regard to antidumping duties.¹⁶ The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.¹⁷

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by TAK for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the original less-than-fair-value (LTFV) investigation (i.e., 16.27 percent) if there is no rate for the intermediate

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 87 FR 61278 (October 11, 2022).

² See Memorandum, "Extension of the Deadline for Preliminary Results of Antidumping Duty Administrative Review, dated April 26, 2023.

³ See Memorandum, "Decision Memorandum for the Preliminary Results of the 2021–2022 Administrative Review of the Antidumping Duty Order on Low Melt Polyester Staple Fiber from the Republic of Korea," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁴ See *Low Melt Polyester Staple Fiber from the Republic of Korea and Taiwan: Antidumping Duty Orders*, 83 FR 40752 (August 16, 2018) (*Order*).

⁵ See 19 CFR 351.224(b).

⁶ See 19 CFR 351.309(c).

⁷ See 19 CFR 351.309(c); see also *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID-19; Extension of Effective Period*, 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

⁸ See 19 CFR 351.309(c)(2) and (d)(2).

⁹ See 19 CFR 351.303.

¹⁰ See *Temporary Rule*.

¹¹ See 19 CFR 351.310(c).

¹² See 19 CFR 351.310(d).

¹³ See section 751(a)(3)(A) of the Act.

¹⁴ See 19 CFR 351.212(b).

¹⁵ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

¹⁶ *Id.* at 8102.

¹⁷ See section 751(a)(2)(C) of the Act.

company(ies) involved in the transaction.¹⁸

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the company listed above will be equal to the weighted-average dumping margin established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the LTFV investigation, but the producer is, then the cash deposit rate will be the cash deposit rate established in the completed segment for the most recent period for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 16.27 percent, the all-others rate established in the LTFV investigation.¹⁹ These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in

Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: June 26, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Discussion of the Methodology
- V. Recommendation

[FR Doc. 2023–13953 Filed 6–29–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 230612–0147]

Draft Plan for Providing Public Access to the Results of Federally Funded Research

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice; request for public comment.

SUMMARY: The National Institute of Standards and Technology seeks comments on the *Draft NIST Plan for Providing Public Access to the Results of Federally Funded Research*. NIST is taking steps to make its scientific data and publications more readily available and accessible by the public, as directed in an August 2022 memorandum from the Office of Science and Technology Policy. The NIST Public Access Plan applies to the results of research funded wholly or in part by NIST, presented in peer-reviewed scholarly publications and as research data. This document outlines NIST's plan for implementing new requirements to manage the public access of scientific data and publications. Public comments received on the NIST Public Access Plan will inform NIST as it revises its existing directives to implement the updated Plan.

DATES: Responses must be received by 11:59 p.m. Eastern Time on August 14, 2023 to be considered.

ADDRESSES: Comments may be submitted by either of the following methods:

- **Electronic submission:** Submit electronic public comments via the Federal eRulemaking Portal.
 1. Go to www.regulations.gov and enter NIST–2023–0002 in the search field.
 2. Click the “Comment Now!” icon, complete the required fields.
 3. Enter or attach your comments.
- **By email:** Comments in electronic form may also be sent to public-access@nist.gov in any of the following formats: HTML, ASCII, Word, RTF, or PDF.
- **By post:** Comments may be sent by mail to Katherine Sharpless, NIST, 100 Bureau Drive, Stop 4701, Gaithersburg, MD 20899–4701.

Please submit comments only and include your name, organization's name (if any), and cite “NIST Public Access Plan” in all correspondence. Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials.

All comments responding to this document will be a matter of public record. Relevant comments will generally be available on the Federal eRulemaking Portal at <https://www.Regulations.gov> and, after the comment period closes, on NIST's website at <https://www.nist.gov/open>. NIST will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

FOR FURTHER INFORMATION CONTACT: For questions about this notice contact: Katherine Sharpless, Open Access Officer, email address katherine.sharpless@nist.gov, (301) 975–3121. Please direct media inquiries to NIST's Office of Public Affairs at (301) 975–2762.

SUPPLEMENTARY INFORMATION: The National Institute of Standards and Technology (NIST) is one of our Nation's oldest Federal laboratories (for more information, visit www.nist.gov). A bureau in the Department of Commerce, the NIST mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. From early electrical

¹⁸ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

¹⁹ See *Order*.

measurement research to today's quantum information science, NIST has long been, and continues to be, a center for high-impact research meeting the needs of academia, industry, and government. The NIST laboratories conduct world-class research, often in close collaboration with industry, which advances the nation's technology infrastructure and helps U.S. companies continually improve products and services.

NIST publishes this notice to seek comments on the *Draft NIST Plan for Providing Public Access to Results of Federally Funded Research*, posted at www.nist.gov/open. NIST developed a public access plan in response to the February 22, 2013, Office of Science and Technology Policy (OSTP) memorandum *Increasing Access to the Results of Federally Funded Scientific Research* and several White House memoranda (*i.e.*, Office of Management and Budget memoranda M-10-06 *Open Government Directive* and M-13-13 *Open Data Policy—Managing Information as an Asset*). NIST policy was developed from that original plan; NIST's public access policy has been operational since 2015. NIST's original plan and the resultant policy ensured that the integrity of NIST data are maintained throughout their life cycle and increased the visibility of NIST measurements, standards, technology, and research activities.

On August 25, 2022, OSTP issued a new public access memorandum, *Ensuring Free, Immediate, and Equitable Access to Federally Funded Research*. In response to OSTP's 2022 memo, NIST is taking new steps to make its scientific data and publications more readily available and accessible by the public.

The *Draft NIST Plan for Providing Public Access to the Results of Federally Funded Research* applies to the results of research funded wholly or in part by NIST, presented in peer-reviewed scholarly publications and as research data. The document outlines NIST's plan to manage public access to research data and publications in accordance with new recommendations of the 2022 OSTP memo, including the removal of embargo periods for access to publications resulting from NIST-funded work, requiring immediate release of data associated with narrative publications, inclusion of available persistent identifiers in publications, and emphasis on the need for accessibility to users who have disabilities through provision of machine-readable publications. The NIST Public Access Plan was reviewed by the Office of Science and Technology

Policy and the Office of Management and Budget, and those comments have been addressed in the plan being posted for comment.

NIST invites respondents to comment on the following questions that pertain to the implementation NIST's updated public access plan:

- How can NIST ensure equity in publication opportunities?
- How can NIST ensure public access and accessibility to outputs of NIST-funded research?
- How can NIST monitor impacts on affected communities—authors and readers alike?
- How can NIST improve the plan to provide greater public access to NIST-funded research results?

Comments relating to the text of the *Draft NIST Plan for Providing Public Access to the Results of Federally Funded Research* should reference the document by page and line number. All comments must be received in accordance with the **DATES** and **ADDRESSES** sections of the notice above.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023-13866 Filed 6-29-23; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD120]

Council Coordination Committee Meeting

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

ACTION: Notice of a public meeting; information regarding the agenda.

SUMMARY: The National Marine Fisheries Service, Office of Sustainable Fisheries, will host an interim session of the Council Coordination Committee (CCC), consisting of the Regional Fishery Management Council chairs, vice chairs, and executive directors, on July 17, 2023. The intent of this virtual meeting is to discuss priorities and process for distributing funds provided under the Inflation Reduction Act (IRA) to the Councils for climate-ready fisheries and to describe the agencies planned investment in various scientific data collection, processing, and analysis efforts with IRA funds.

DATES: The meeting will begin at 4 p.m. Eastern Daylight Time (EDT) on Monday, July 17, adjourning at 5:30 p.m. EDT.

ADDRESSES: The meeting will be held online via WebEx. Webinar information to join the meeting can be found at <https://www.fisheries.noaa.gov/national/partners/council-coordination-committee>.

FOR FURTHER INFORMATION CONTACT:

Morgan Corey by email at Morgan.Corey@noaa.gov or at (301) 427-8500.

SUPPLEMENTARY INFORMATION: The IRA is a historic, Federal Government-wide investment that furthers efforts to build a Climate-Ready Nation. NMFS will receive an unprecedented investment to strengthen the agency's core mission to provide science-based management and conservation of the Nation's marine resources as we confront climate change.

During this interim CCC session, NMFS will outline the process for providing IRA funding to the Councils to advance climate-ready fisheries management. Actions funded under IRA for the Councils sub-component will contribute to the following goals: implementation of fishery management measures necessary to improve climate resiliency and responsiveness to climate impacts, and development and advancement of climate-related fisheries management planning and implementation efforts in support of underserved communities.

In addition, NMFS will provide an overview of how IRA funding will be used in the Data Acquisition and Management sub-component. Actions funded under this sub-component will use advanced technologies, including data management, to improve and expand observation and sampling capabilities of critical fish, protected species, ecosystem, and climate data in order to understand where climate-driven shifts in distribution of fish and other key living marine resources are occurring.

The 2007 reauthorization of the Magnuson-Stevens Fishery Conservation and Management Act established the CCC. The CCC consists of the chairs, vice chairs, and executive directors of each of the eight Regional Fishery Management Councils.

Proposed Agenda

Monday, July 17, 2023—4 p.m.–5:30 p.m. EDT

1. Data Acquisition and Management Funding Overview & Discussion
2. Regional Fishery Management Councils Funding Overview & Discussion
3. Public Comment
4. Close of Meeting

Special Accommodations

If you have particular access needs please contact Morgan Corey at Morgan.Corey@noaa.gov at least 7 business days prior to the meeting for accommodation.

Dated: June 27, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023-13991 Filed 6-29-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD066]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to San Francisco Bay Area Water Emergency Transportation Authority's Ferry Terminal Refurbishment in Alameda, California

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the San Francisco Bay Area Water Emergency Transportation Authority (WETA) for authorization to take marine mammals incidental to the refurbishment of the Alameda Main Street Ferry Terminal in Alameda, California. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than July 31, 2023.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National

Marine Fisheries Service and should be submitted via email to ITP.clevenstine@noaa.gov.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

Alyssa Clevenstine, Office of Protected Resources, NMFS, (301) 427-8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to

rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as “mitigation”); and requirements pertaining to the mitigation, monitoring, and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our proposed action (*i.e.*, the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On February 9, 2023, NMFS received a request from WETA for an IHA to take marine mammals incidental to pile removal and driving associated with refurbishment of the Alameda Main Street Ferry Terminal in Alameda, California. Following NMFS' review of the application, WETA submitted revised versions on March 15, April 18, May 18, and May 24, 2023. The application was deemed adequate and complete on May 25, 2023. WETA's request is for take of harbor seals (*Phoca vitulina*) and California sea lions (*Zalophus californianus*) by Level A harassment and Level B harassment. Neither WETA nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity*Overview*

WETA proposes to refurbish the Alameda Main Street Ferry Terminal in the Oakland Inner Harbor, Alameda, California, to update and replace ageing ferry terminal components and structural support. Water depth within the project area varies between 14–28 inches (in; 35.56–71.12 centimeter (cm)) mean lower low water (MLLW), and most construction activities will occur above or at the waterline. The only elements that would extend below the mudline are nine new steel piles that would have a maximum tip elevation of approximately 110 in MLLW. WETA intends to use vibratory extraction to remove four existing 30 in (76.2 cm) steel guide piles and vibratory installation to drive nine new steel piles: two 24 in (60.9 cm) steel pipe piles with concrete cap beams on land, one 48 in (121.9 cm) steel pipe monopile in water, four 36 in (91.4 cm) steel guide piles in water, and two 36 in (91.4 cm) donut fender piles in water. A maximum of 6 days of consecutive piling activities is proposed to occur

during the course of construction (4–6 weeks) from August through November 2023. WETA proposes to use vibratory pile driving and, if necessary, impact pile driving to achieve required tip elevation for the nine new piles. No in-air impacts to marine mammals are anticipated from the installation of the two 24 in (60.9 cm) piles driven on land, as such, they were not included in the Estimated Take section and will not be discussed further.

Project construction would include replacement of the existing bridge walkway and foundation, replacement of the gangway, demolition and replacement of the float, removal and installation of guide piles, and upgrades to utilities at the project site. No take of marine mammals is anticipated to occur incidental to these portions of the project and these activities will not be discussed further.

Dates and Duration

This IHA would be effective from August 15, 2023, until August 14, 2024. Pile extraction and installation activities would occur for a total of 6 consecutive days (5 days in water, 1 day on land)

from August through November 2023. WETA plans to conduct piling activities during daylight hours, with noise-generating construction activities limited to occur between the hours of 0700–1900 Monday through Friday, and 0800–1300 Saturdays. Due to in-water work timing restrictions to protect ESA-listed fish species, all in-water construction activities including pile extraction and installation would occur during the period from June 1 to November 30. Pile extraction is anticipated to take between 1–3 days, pile installation is anticipated to take 3 days, of which 2 days will be required for in-water pile installation.

Specific Geographic Region

This project will be located at the existing Alameda Main Street Ferry Terminal in Alameda, CA (Figure 1), at a water depth between 14–28 in (35.56–71.12 cm). All project activities for which take is being requested will be located in the Oakland Inner Harbor, Alameda (see Figure 2 in IHA application).

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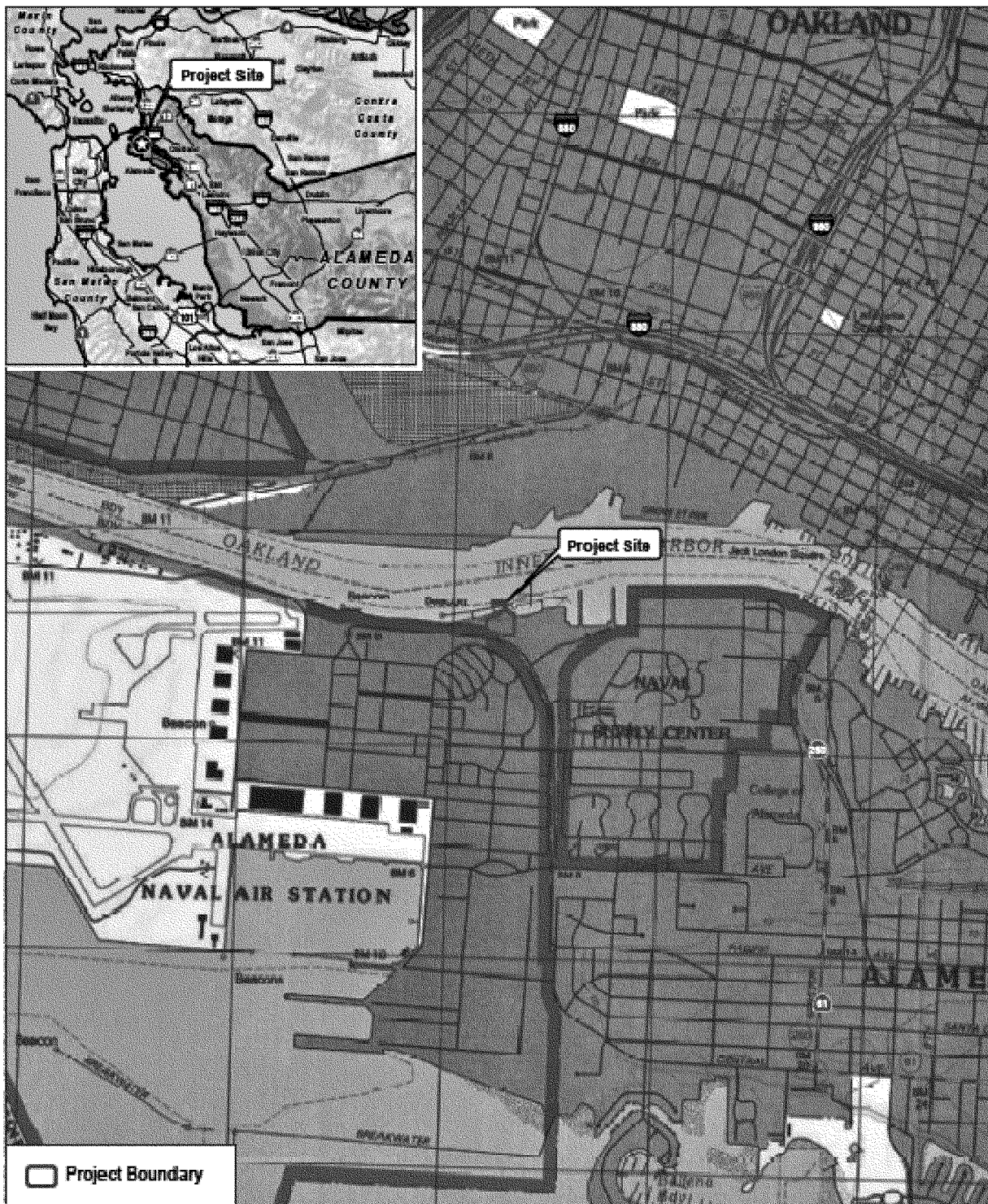


Figure 1 – Project Area Map

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Detailed Description of the Specified Activity

Vibratory extraction of four existing 30 in diameter steel guide piles would occur over 1 to 3 days. Vibratory

installation of one 48 in diameter steel pipe monopile, four 36 in diameter steel guide piles, and two 36 in diameter donut fender piles would occur over 2 days, with the monopile requiring 1 day and the six 36 in piles requiring 1 day. Impact installation of the seven new

piles would occur only if required tip elevation was not achieved through vibratory methods and a bubble curtain would be employed to attenuate noise from impact driving (assuming a 5-dB reduction).

TABLE 1—PILE EXTRACTION AND INSTALLATION ACTIVITIES

Pile activity	Structure	Pile size (in)	Piles per day	Duration of activity	Duration of vibratory activity per pile (minutes)	Estimated blows of impact driving per pile (strikes) *
Extraction	Removal of existing guide piles ..	30	4	1–3 days	45	N/A
Installation	Terminal bridge and foundation replacement.	48	1	1 day	45	1,015
Installation	Float replacement (guide piles and donut fender piles).	36	6	1 day	45	1,015

Note: Impact pile installation will only be used if vibratory methods are insufficient to achieve required tip elevation.

* Impact pile driving assumes approx. 20–30 minutes of driving.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments) and more general information about these species

(e.g., physical and behavioral descriptions) may be found on NMFS' website (<https://www.fisheries.noaa.gov/find-species>).

Table 2 lists all species for which take is expected and proposed to be authorized for this activity, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality from anthropogenic sources are

included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Pacific SARs. All values presented in Table 2 are the most recent available at the time of publication (including from the draft 2022 SARs) and are available online at: www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.

TABLE 2—MARINE MAMMAL SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES ¹

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Carnivora—Pinnipedia						
<i>Family Otariidae (eared seals and sea lions):</i> California sea lion	<i>Zalophus californianus</i>	U.S.	-/-; N	257,606 (N/A; 233,515; 2014).	14,011	>321
<i>Family Phocidae (earless seals):</i> Harbor seal	<i>Phoca vitulina richardii</i>	California	-/-; N	30,968 (0.157; 27,348; 2012)	1,641	42.8

¹ Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/>; Committee on Taxonomy (2022)).

² Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

³ NMFS marine mammal stock assessment reports online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

⁴ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, vessel strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range.

As indicated above, both species in Table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur and

are also included in Table 2 of the IHA application. No other marine mammal species are expected to occur in the project area.

California Sea Lion

California sea lions occur from Vancouver Island, British Columbia, to the southern tip of Baja California,

Mexico. Sea lions breed on the offshore islands of southern and central California from May through July (Heath and Perrin, 2009). During the non-breeding season, adult and sub-adult males and juveniles migrate northward along the coast to central and northern California, Oregon, Washington, and Vancouver Island (Jefferson *et al.*, 1993). They return south the following spring (Heath and Perrin, 2009, Lowry and Forney, 2005). Females and some juveniles tend to remain closer to rookeries (Antonelis *et al.*, 1990, Melin *et al.*, 2008).

Pupping occurs primarily on the California Channel Islands from late May until the end of June (Peterson and Bartholomew, 1967). No pupping has been recorded in the San Francisco Bay. Weaning and mating occur in late spring and summer during the peak upwelling period (Bograd *et al.*, 2009). After the mating season, adult males migrate northward to feeding areas as far away as the Gulf of Alaska (Lowry *et al.*, 1992), and they remain away until spring (March through May), when they migrate back to the breeding colonies. Adult females generally remain south of Monterey Bay, California, throughout the year, feeding in coastal waters in the summer and offshore waters in the winter, alternating between foraging and nursing their pups on shore until the next pupping/breeding season (Melin and DeLong, 2000, Melin *et al.*, 2008).

California sea lions experienced an Unusual Mortality Event (UME), not correlated to an El Niño event, from 2013–2017 (Carretta *et al.*, 2022). Pup and juvenile age classes experienced high mortality during this time, likely attributed to sea lion prey availability, specifically Pacific sardines (*Sardinops sagax*). California sea lions are also susceptible to the algal neurotoxin domoic acid (Carretta *et al.*, 2022). This neurotoxin is expected to cause future mortalities among California sea lions due to the prevalence of harmful algal blooms within their habitat.

In San Francisco Bay, sea lions haul out primarily on floating docks at Pier 39 at the Fisherman's Wharf area of the San Francisco Marina, approximately 10.5 kilometers (6.5 miles) west-northwest of the project area. Haul out numbers at Pier 39 vary seasonally. In addition to the Pier 39 haul out, California sea lions haul out on buoys, wharfs, and similar structures throughout the Bay.

Harbor Seal

Harbor seals are distributed from Baja California, Mexico, to the eastern Aleutian Islands of Alaska (Harvey and Goley, 2011). Harbor seals do not make extensive pelagic migrations but may travel hundreds of kilometers to find food or suitable breeding areas (Harvey and Goley, 2011, Carretta *et al.*, 2022). Seals primarily haul out on remote mainland and island beaches, reefs, and estuary areas. At haulout sites, they congregate to rest, socialize, breed, and molt. In California, there are approximately 500 haulout sites along the mainland and on offshore islands, including intertidal sandbars, rocky shores, and beaches (Hanan, 1996, Lowry *et al.*, 2008).

Harbor seals are opportunistic, generalist foragers and are expected to forage in shallow, intertidal waters on a variety of fish, crustaceans, and other species in the San Francisco Bay and could occasionally be found foraging in the Oakland Inner Harbor (Gibble, 2011). Harbor seals haul out at approximately 20 locations in San Francisco Bay with three main locations: Mowry Slough in the south, Corte Madera Marsh and Castro Rocks in the north, and Yerba Buena Island in the central bay (Gibble, 2011, Grigg *et al.*, 2012).

Harbor seals are the most common marine mammal species observed in the San Francisco Bay, where they primarily haul out on exposed rocky ledges and on sloughs in the southern San Francisco Bay. Harbor seals are central-place foragers (Orlans, 1979) and tend to exhibit strong site fidelity within season and across years, generally forage close to haulout sites, and repeatedly visit specific foraging areas (Grigg *et al.*, 2012, Suryan and Harvey, 1998, Thompson *et al.*, 1998). Harbor seals in San Francisco Bay forage mainly within 7 mi (10 km) of their primary haulout site (Grigg *et al.*, 2012), and often within just 1–3 mi (1–5 km; Torok, 1994). Depth, bottom relief, and prey abundance also influence foraging location (Grigg *et al.*, 2012).

Peak numbers of harbor seals haul out in central California during late May to early June, which coincides with the peak molt (May through June). During both pupping and molting seasons, the number of seals and the length of time hauled out per day increase, from an average of 7 hours per day to 10–12 hours per day (Harvey and Goley, 2011,

Huber *et al.*, 2001, Stewart and Yochem, 1994). Pupping occurs from March through May in central California and pups are weaned in approximately 4 weeks, most by mid-June (Codde and Allen, 2018). The closest recognized harbor seal pupping site to the proposed project area is at Castro Rocks, approximately 12 mi (19 km) away.

Harbor seals tend to forage at night and haul out during the day with a peak in the afternoon between 1300 and 1600 hr (Grigg *et al.*, 2012, London *et al.*, 2002, Stewart and Yochem, 1994, Yochem *et al.*, 1987). Tide levels affect the maximum number of seals hauled out, with the largest number of seals hauled out at low tide, but time of day and season have the greatest influence on haul out behavior (Manugian *et al.*, 2017, Patterson and Acevedo-Gutiérrez, 2008, Stewart and Yochem, 1994).

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.*, Richardson *et al.*, 1995, Wartzok and Ketten, 1999, Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, etc.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.*, low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS
[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>)	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006, Kastelein *et al.*, 2009, Reichmuth *et al.*, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Acoustic effects on marine mammals during the specified activities can occur from impact pile driving and vibratory pile driving and removal. The effects of underwater noise from WETA's proposed activities have the potential to result in Level A and Level B harassment of marine mammals in the project area.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of

sound from many sources both near and far (American National Standards Institute, 1995). The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.*, waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.*, sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.*, vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise “ambient” or “background” sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.*, 1995). The result is that, depending on the source type and its intensity, sound from the specified activities may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction activities associated with the proposed project would include vibratory pile extraction and vibratory pile installation, with the potential for impact pile installation. The sounds produced by these activities fall into one of two general sound types: impulsive and non-impulsive. Impulsive sounds (*e.g.*, explosions, sonic booms, impact pile driving) are typically transient, brief (less than 1 second), broadband, and consist of high

peak sound pressure with rapid rise time and rapid decay (American National Standards Institute, 1986, NIOSH, 1998, NMFS, 2018). Non-impulsive sounds (*e.g.*, machinery operations such as drilling or dredging, vibratory pile driving, underwater chainsaws, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with rapid rise/decay time that impulsive sounds do (American National Standards Institute, 1995, NIOSH, 1998, NMFS, 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.*, Ward, 1997).

Two types of hammers would be used on this project, vibratory and, if necessary, impact. Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers produce non-impulsive, continuous sounds. Vibratory hammering generally produces sound pressure levels (SPLs) 10–20 dB lower than impact pile driving of the same-sized pile (Oestman *et al.*, 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002, Carlson *et al.*, 2005). Impact hammers operate by repeatedly dropping and/or pushing a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is considered impulsive.

The likely or possible impacts of WETA's proposed activities on marine mammals could be generated from both non-acoustic and acoustic stressors. Potential non-acoustic stressors include the physical presence of the equipment, vessels, and personnel; however, we expect that any animals that approach the project site close enough to be harassed due to the presence of equipment or personnel would be

within the Level B harassment zones from pile removal or driving and would already be subject to harassment from the in-water activities. Therefore, any impacts to marine mammals are expected to primarily be acoustic in nature. Acoustic stressors are generated by heavy equipment operation during pile driving activities (*i.e.*, impact and vibratory pile driving and removal).

Acoustic Impacts

The introduction of anthropogenic noise into the aquatic environment from pile driving equipment is the primary means by which marine mammals may be harassed from WETA's specified activities. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.*, 2007). Generally, exposure to pile driving and removal and other construction noise has the potential to result in auditory threshold shifts (TS) and behavioral reactions (*e.g.*, avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses, such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions, such as communication and predator and prey detection. The effects of pile driving and construction noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.*, impulsive vs. non-impulsive), the species, age and sex class (*e.g.*, adult male vs. mother with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.*, 2004, Southall *et al.*, 2007). Here we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced TS as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). The amount of TS is customarily expressed in dB and TS can be permanent or temporary. As described in NMFS (2018), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.*, impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS,

the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.*, spectral content), the hearing and vocalization frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.*, how animal uses sound within the frequency band of the signal) (Kastelein *et al.*, 2014b), and the overlap between the animal and the source (*e.g.*, spatial, temporal, and spectral).

Permanent Threshold Shift (PTS)—NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Available data from humans and other terrestrial mammals indicate that a 40 dB TS approximates PTS onset (see Ward *et al.*, 1958, Ward *et al.*, 1959, Ward, 1960, Kryter *et al.*, 1966, Miller, 1974, Ahroon *et al.*, 1996, Henderson *et al.*, 2008). PTS levels for marine mammals are estimates, because there are limited empirical data measuring PTS in marine mammals (*e.g.*, Kastak *et al.*, 2008), largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary Threshold Shift (TTS)—TTS is a temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Based on data from cetacean TTS measurements (see Southall *et al.*, 2007), a TTS of 6 dB is considered the minimum TS clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.*, 2000, Finneran *et al.*, 2000, Finneran *et al.*, 2002). As described in Finneran (2016), marine mammal studies have shown the amount of TTS increases with cumulative sound exposure level (SEL_{cum}) in an accelerating fashion: At low exposures with lower SEL_{cum} , the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL_{cum} , the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.*, recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily

compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.*, 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise (*Phocoena phocoena*), Yangtze finless porpoise (*Neophocoena asiaeorientalis*)), and five species of pinnipeds exposed to a limited number of sound sources (*i.e.*, tones and octave-band noise) in laboratory settings (Finneran, 2015). TTS was not observed in trained spotted seals (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth *et al.*, 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.*, a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.*, 2019b, Kastelein *et al.*, 2019a, Kastelein *et al.*, 2020a, Kastelein *et al.*, 2020b). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.*, 2009, Finneran *et al.*, 2010, Kastelein *et al.*, 2014a, Kastelein *et al.*, 2015). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from intermittent exposures such as sonars and impulsive sources.

The potential for TTS from impact pile driving exists. After exposure to playbacks of impact pile driving sounds (rate 2,760 strikes/hour) in captivity, mean TTS increased from 0 dB after a 15 minute exposure to 5 dB after a 360 minute exposure; recovery occurred within 60 minutes (Kastelein *et al.*, 2016). Additionally, the existing marine

mammal TTS data come from a limited number of individuals within these species. No data are available on noise-induced hearing loss for mysticetes. Nonetheless, what we considered is the best available science. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Southall *et al.* (2019), Finneran and Jenkins (2012), Finneran (2015), and Table 5 in NMFS (2018).

Proposed activities for this project include impact and vibratory pile driving, and vibratory pile removal. There would likely be pauses in activities producing the sound during each day. Given these pauses and the fact that many marine mammals are likely moving through the project areas and not remaining for extended periods of time, the potential for TS declines.

Behavioral Harassment—Exposure to noise from pile driving and removal also has the potential to behaviorally disturb marine mammals. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.*, NRC, 2005, Lusseau and Bejder, 2007, Weilgart, 2007b).

Disturbance may result in changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); or avoidance of areas where sound sources are located. Pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.*, species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.*, Richardson *et al.*, 1995, Wartzok *et al.*, 2004, Southall *et al.*, 2007, Weilgart,

2007a, Archer *et al.*, 2010, Southall *et al.*, 2021). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.*, 2012), and can vary depending on characteristics associated with the sound source (*e.g.*, whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see Appendices B and C of Southall *et al.* (2007) as well as Nowacek *et al.* (2007), Ellison *et al.* (2012), and Gomez *et al.* (2016) for a review of studies involving marine mammal behavioral responses to sound.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.*, bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.*, Croll *et al.*, 2001, Nowacek *et al.*, 2004, Madsen *et al.*, 2006, Yazvenko *et al.*, 2007, Melcon *et al.*, 2012). In addition, behavioral state of the animal plays a role in the type and severity of a behavioral response, such as disruption to foraging (*e.g.*, Sivle *et al.*, 2016, Wensveen *et al.*, 2017). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal (Goldbogen *et al.*, 2013).

Stress responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.*, Selye, 1950, Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity.

These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.*, Moberg, 1987, Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.*, 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and "distress" is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments for both laboratory and free-ranging animals (*e.g.*, Holberton *et al.*, 1996, Hood *et al.*, 1998, Jessop *et al.*, 2003, Krausman *et al.*, 2004, Lankford *et al.*, 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000, Romano *et al.*, 2002b) and, more rarely, studied in wild populations (*e.g.*, Romano *et al.*, 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced vessel traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as "distress." In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003), however distress is an unlikely

result of these projects based on observations of marine mammals during previous, similar projects in the area.

Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (e.g., those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.*, 1995). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (e.g., snapping shrimp, wind, waves, precipitation) or anthropogenic (e.g., pile driving, shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (e.g., signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (e.g., sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions. Masking of natural sounds can result when human activities produce high levels of background sound at frequencies important to marine mammals. Conversely, if the background level of underwater sound is high (e.g., on a day with strong wind and high waves), an anthropogenic sound source would not be detectable as far away as would be possible under quieter conditions and would itself be masked. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (e.g., Clark *et al.*, 2009) and may result in energetic or other costs as animals change their vocalization behavior (e.g., Miller *et al.*, 2000, Foote *et al.*, 2004, Parks *et al.*, 2007, Di Iorio and Clark, 2010, Holt *et al.*, 2009). The Bay is heavily used by commercial, recreational, and military vessels, and background sound levels in the area are already elevated. Due to the transient nature of marine mammals to move and avoid disturbance, masking is not likely to have long-term impacts on marine mammal species within the proposed project area.

Airborne Acoustic Effects—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving and removal that have the potential to cause behavioral harassment, depending on their distance from pile driving activities.

Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above the acoustic criteria. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, there are no known haul out sites in the vicinity of the project area and, if there were, these animals would likely previously have been "taken" because of exposure to underwater sound above the behavioral harassment thresholds, which are generally larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Marine Mammal Habitat Effects

WETA's proposed construction activities could have localized, temporary impacts on marine mammal habitat, including prey, by increasing in-water SPLs and slightly decreasing water quality. Increased noise levels may affect acoustic habitat (see masking discussion above) and adversely affect marine mammal prey in the vicinity of the project areas (see discussion below). During impact and vibratory pile driving or removal, elevated levels of underwater noise would ensonify the project area where both fishes and mammals occur, and could affect foraging success. Additionally, marine mammals may avoid the area during construction, however, displacement due to noise is expected to be temporary and is not expected to result in long-term effects to the individuals or populations. Construction activities are expected to be of short duration and would likely have temporary impacts on marine mammal habitat through increases in underwater and airborne sound.

A temporary and localized increase in turbidity near the seafloor would occur in the immediate area surrounding the area where piles are installed or removed. In general, turbidity

associated with pile driving is localized to about a 25-ft (7.6-m) radius around the pile (Everitt *et al.*, 1980). Cetaceans are not expected to be close enough to the pile driving areas to experience effects of turbidity, and any pinnipeds could avoid localized areas of turbidity. Local currents are anticipated to disburse any additional suspended sediments produced by project activities at moderate to rapid rates depending on tidal stage. Therefore, we expect the impact from increased turbidity levels to be discountable to marine mammals and do not discuss it further.

In-Water Construction Effects on Potential Foraging Habitat—The area likely impacted by the proposed action is relatively small compared to the total available habitat in the Bay. The proposed project area is highly influenced by anthropogenic activities and provides limited foraging habitat for marine mammals. Furthermore, pile driving and removal at the proposed project site would not obstruct long-term movements or migration of marine mammals.

Avoidance by potential prey (i.e., fish) of the immediate area due to the temporary loss of this foraging habitat is also possible. The duration of fish and marine mammal avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. Any behavioral avoidance by prey of the disturbed area would still leave significantly large areas of potential foraging habitat in the nearby vicinity.

In-Water Construction Effects on Potential Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (e.g., crustaceans, cephalopods, fish, zooplankton, other marine mammals). Marine mammal prey varies by species, season, and location. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (Zelick *et al.*, 1999, Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.*, 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing

sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (e.g., feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish; several are based on studies in support of large, multiyear bridge construction projects (e.g., Scholik and Yan, 2001, Popper and Hastings, 2009). Many studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (e.g., Pearson *et al.*, 1992, Skalski *et al.*, 1992, Santulli *et al.*, 1999, Fewtrell and McCauley, 2012, Paxton *et al.*, 2017). In response to pile driving, Pacific sardines and northern anchovies (*Engraulis mordax*) may exhibit an immediate startle response to individual strikes, but return to “normal” pre-strike behavior following the conclusion of pile driving with no evidence of injury as a result (see NAVFAC, 2014). However, some studies have shown no or slight reaction to impulse sounds (e.g., Wardle *et al.*, 2001, Popper *et al.*, 2005, Jorgenson and Gyselman, 2009, Peña *et al.*, 2013).

SPLs of sufficient strength have been known to cause injury to fish and fish mortality. However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.*, 2012a, Casper *et al.*, 2013).

The greatest potential impact to fish during construction would occur during

impact pile driving. However, the duration of impact pile driving would be limited to a contingency in the event that vibratory driving does not satisfactorily install the pile. In-water construction activities would only occur during daylight hours allowing fish to forage and transit the project area in the evening. Vibratory pile driving may elicit behavioral reactions from fish such as temporary avoidance of the area but is unlikely to cause injuries to fish or have persistent effects on local fish populations. In addition, it should be noted that the area in question is low-quality habitat since it is already highly developed and experiences a high level of anthropogenic noise from normal dock operations and other vessel traffic.

The most likely impact to fishes from pile driving and removal and construction activities at the project area would be temporary behavioral avoidance of the area. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary. Further, it is anticipated that preparation activities for pile driving or removal (i.e., positioning of the hammer) and upon initial startup of devices would cause fish to move away from the affected area outside areas where injuries may occur. Therefore, relatively small portions of the proposed project area would be affected for short periods of time, and the potential for effects on fish to occur would be temporary and limited to the duration of sound-generating activities.

In summary, given the short daily duration of sound associated with individual pile driving events and the relatively small areas being affected, pile driving activities associated with the proposed actions are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. Any behavioral avoidance by fish of the disturbed area would still leave significantly large potential areas fish and marine mammal foraging habitat in the nearby vicinity. Thus, we conclude that impacts of the specified activities are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of “small numbers,” and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines “harassment” as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the acoustic sources (i.e., vibratory removal, vibratory driving, impact driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for PTS (Level A harassment) to result, primarily for phocids because predicted auditory injury zones are larger than for otariids. Auditory injury is unlikely to occur for otariids. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

Generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (e.g., previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (e.g., frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (e.g., bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (e.g., Southall *et al.*, 2007, Southall *et al.*, 2021, Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a

generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 microPascal (re 1 μ Pa)) for continuous (e.g., vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (e.g., seismic airguns) or intermittent (e.g., scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

WETA's proposed activity includes the use of continuous (vibratory pile removal and installation) and, potentially, impulsive (impact pile installation) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μ Pa are applicable.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). WETA's proposed activity includes the use of impulsive (impact hammer) and non-impulsive (vibratory hammer) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	Cell 4: $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	Cell 6: $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW)(Underwater)	Cell 7: $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	Cell 8: $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW)(Underwater)	Cell 9: $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	Cell 10: $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μ Pa, and cumulative sound exposure level (L_E) has a reference value of 1 μ Pa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

Pile driving activities, using an impact hammer as well as a vibratory hammer, would generate underwater noise that could result in disturbance to marine mammals near the project area. A review of underwater sound measurements for similar projects was

conducted to estimate the near-source sound levels for impact and vibratory pile driving and vibratory extraction. Source levels for proposed removal and installation activities derived from this review are shown in Table 5.

TABLE 5—PROJECT SOUND SOURCE LEVELS

Driving method	Location	Pile size (in)	Peak SPL dB re 1 µPa	RMS SPL dB re 1 µPa	SEL dB re 1 µPa	Source
Impact *	Water	36	206	188	178	Caltrans 2020
Impact *	Water	48	208	187	174	Caltrans 2020
Vibratory	Water	** 30	200	168	168	POA 2016
Vibratory	Water	36	200	168	168	POA 2016
Vibratory	Water	48	200	168	168	POA 2016

* Attenuated condition achieved using a bubble curtain system for all impact pile driving; attenuated condition assumes a 5-dB reduction in sound.

** Vibratory driving of 36 in piles used as proxy for vibratory extraction of 30 in piles.

Level B Harassment Zone—

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition topography. The general formula for underwater TL is:

$$TL = B * \log_{10} (R_1/R_2),$$

where

TL = transmission loss in dB;

B = transmission loss coefficient;

R₁ = the distance of the modeled SPL from the driven pile; and

R₂ = the distance from the driven pile of the initial measurement.

The recommended TL coefficient for most nearshore environments is the practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, known as practical spreading, which is the most appropriate assumption for WETA's proposed activity in the absence of specific modeling and site-specific information. If piles are installed or removed with a vibratory hammer, the SEL_{cum} thresholds apply for sounds greater than 150 dB (re 1 µPa²-sec) SEL and the peak PTS thresholds that apply to marine mammals would not be reached (see Appendix A in the IHA

application). Sound propagation in the Oakland Inner Harbor is limited by bends in the Oakland estuary. Substantial sound is not anticipated to travel beyond 4,200 m (13,780 ft) to the west (out the shipping channel into the bay) and 1,700 m (5,577 ft) east of the project site (where the channel bends around the island of Alameda), and will be confined to the north and south by the narrow channel of the Oakland Inner Harbor (Figure 1). Therefore, the distance for noise impacts would be limited to 4,200 m west and 1,700 m east. The Level A shutdown zones and Level B harassment zone for WETA's proposed activities are shown in Table 6.

TABLE 6—DISTANCE TO THE LEVEL A AND LEVEL B HARASSMENT THRESHOLDS FOR PROPOSED PILE-DRIVING ACTIVITIES

Method	Pile type	Pile size (in)	Level A threshold for phocids (m)	Level A threshold for otariids (m)	Level B harassment zone (m)
Impact, installation	Steel	36	827	60	736
Impact, installation	Steel	48	136	10	631
Vibratory, extraction *	Steel	30	33	10	4,200 W; 1,700 E
Vibratory, installation *	Steel	36	33	10	4,200 W; 1,700 E
Vibratory, installation *	Steel	48	10	10	4,200 W; 1,700 E

Note: Vibratory driving of 36 in piles used as proxy for vibratory extraction of 30 in piles.

* Constrained by bends in the Oakland Estuary and relatively shallow bathymetry near the shipping channel: 4,200 m (13,780 ft) west, 1,700 m (5,577 ft) east.

Level A Harassment Thresholds—The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some

degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources (*i.e.*, vibratory and impact piling), the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. Inputs used in the optional User Spreadsheet tool, and the resulting estimated isopleths, are reported in Table 7. The isopleths generated by the

User Spreadsheet used the same TL coefficients as the Level B harassment zone calculations, as indicated above for each activity type. Inputs used in the User Spreadsheet (*e.g.*, number of piles per day, duration and/or strikes per pile) are presented in Table 1. The maximum RMS SPL, SEL, and peak SPL are reported in Table 7. The cumulative SEL and peak SPL were used to calculate Level A harassment isopleths for vibratory pile driving and extraction activities, while the single strike SEL value was used to calculate Level A isopleths for impact pile driving activity.

TABLE 7—SOUND LEVELS USED FOR PREDICTING UNDERWATER SOUND IMPACTS

Driving method	Location	Pile size (in)	Peak SPL dB re 1 μ Pa	RMS SPL dB re 1 μ Pa	SEL dB re 1 μ Pa	Peak SPL attenuated* dB re 1 μ Pa	RMS SPL attenuated* dB re 1 μ Pa	SEL attenuated* dB re 1 μ Pa
Impact	Water	36	211	193	183	206	188	178
Impact	Water	48	213	192	179	208	187	174
Vibratory	Water	36	200	168	168	NA	NA	NA
Vibratory	Water	48	200	168	168	NA	NA	NA

Note: Using estimates for vibratory installation of 36 in (91.4 cm) steel pile as proxy for vibratory extraction of 30 in (76.2 cm) steel pile. Sound pressure levels (SPL) measured in dB re 1 μ Pa at 10 meters.

* Attenuated condition assumes minimum 5 dB lower sounds.

NA: sounds from piles driven on land cannot be further attenuated.

Marine Mammal Occurrence

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

The California Department of Transportation (Caltrans) conducted monitoring of marine mammals in the vicinity of the San Francisco-Oakland Bay Bridge for 16 years. From those data, Caltrans has produced at-sea density estimates for California sea lions and harbor seals (Caltrans, 2016). Using these density estimates and the estimated Level A and Level B harassment areas, take estimates were calculated for all potential construction options. Activities and potential animal exposure to Level A harassment levels are presented in the IHA application's Table 3 for phocid species and Table 4 for otariid species. Take estimates based on exposure and activity duration are provided in Tables 5 and 6 of the IHA application.

WETA ferry boat captains have reported frequently seeing both California sea lions and harbor seals in the estuary channel and within the Oakland Inner Harbor (in-water sightings, not hauled out) but did not report seeing either species or other marine mammals near the Alameda Main Street Ferry Terminal dock or platform (WETA, pers. comm.).

California sea lion—Caltrans at-sea density estimate for California sea lions is 0.161 animals/km² for the summer-late fall season (Caltrans, 2016). During El Niño Southern Oscillation (ENSO) conditions, the density of California sea lions in San Francisco Bay may be much greater than the value used above. The likelihood of ENSO conditions developing in 2023 is probable. To account for the potential increase in California sea lions within San Francisco Bay during the proposed project, daily take estimated has been increased by a factor of 10 for each pile activity and type (e.g., 82 FR 17799, April 13, 2017). California sea lions

have occupied docks near Pier 39 in San Francisco, several miles from the project area, since 1987. The highest number of sea lions recorded at Pier 39 was 1,701 individuals in November 2009. Occurrence of sea lions here is typically lowest in June (during pupping and breeding seasons) and highest in August. Approximately 85 percent of the animals that haul out at this site are males, and no pupping has been observed here or at any other site in San Francisco Bay. Pier 39 is the only regularly used haul out site in the project vicinity, but sea lions occasionally haul out on human-made structures such as bridge piers, jetties, or navigation buoys (Riedman, 1990).

Harbor seal—Caltrans at-sea density estimate for harbor seals is 3.957 animals/km² (Caltrans, 2016). No resident harbor seals occur within the Oakland Inner Harbor. The closest haul out to the proposed project area is located outside of the Oakland Inner Harbor at Alameda Point (approx. 37.770127°, -120.296819°), where a float was installed by WETA in 2016 to accommodate harbor seals. This haulout can carry approximately 80 individuals, with highest sightings occurring during winter months. Additionally, the southern shoreline of Yerba Buena Island is a haulout site with the highest numbers hauled out during afternoon low tides in fall and winter months.

Take Estimation

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization.

Incidental take is estimated for each species by estimating the maximum number of marine mammals potentially present within a harassment zone during active pile driving based on density estimates, harassment zone size, and length of construction activity. Animal exposure estimates for each species were calculated by multiplying the estimated density of each species by the area of each harassment zone during

active each type of pile driving activity (vibratory removal, vibratory driving, impact driving) and pile size (30 in, 36 in, 48 in). The estimated density is based on Caltrans (2016) offshore at-sea density and increased to account for the likely increase of animals in a nearshore environment based on previous comments from the Marine Mammal Commission (see Tables 3, 4 in application and 82 FR 17799, April 13, 2017).

Maximum number of animals exposed per activity = Density $\times$ Level A or Level B harassment area

Estimated take was calculated using the exposure estimate multiplied by the number of days each in-water pile driving activity will occur. An additional take of 0–2 animals per day was added to account for the potential occurrence of small groups or additional individuals. This was done because small numbers of both species are known to incidentally use the Oakland Inner Harbor but extensive surveys have not been completed in the proposed project area. Using these density estimates and the areas within the Level A and B harassment isopleths, the take estimates were calculated for all possible construction options and here we show the maximum take estimates. Maximum estimated take by Level A harassment is based on 3 days of in-water vibratory pile removal plus 2 days of in-water impact driving, as the Level A harassment isopleth is larger for impact driving than vibratory driving (Table 8). Maximum estimated take by Level B harassment is based on 3 days of in-water vibratory removal plus 2 days of in-water vibratory pile installation, as the Level B harassment isopleth for vibratory driving is larger than for impact driving (Table 9). This results in a conservative estimate of how many marine mammals might be present to ensure that take estimates will not be exceeded (Table 10).

Estimated take = Maximum number of animals exposed $\times$ number of days per activity + additional individuals

Finally, due to the probability of ENSO conditions developing throughout 2023 (https://www.cpc.ncep.noaa.gov/products/analysis_monitoring/enso_advisory/

ensodisc.shtml), the daily take estimate for California sea lions was multiplied by a factor of 10 for each day to account for a potential increase in occurrence that has been previously documented

for the species under expected climatological conditions (see 82 FR 17799, April 13, 2017).

TABLE 8—ESTIMATED TAKE BY LEVEL A HARASSMENT PER ACTIVITY

Construction activity	Pile size (in)	Species	Potential take/day	Duration of activity (day)	Estimated incidental take	Additional level A take requested (animals/day)	Total level A take
Vibratory removal	*30	HASE	0.04	1–3	<1	1	1–3
Vibratory removal	*30	CASL	NA	1–3	NA	NA	NA
Vibratory installation	36	HASE	0.04	1	<1	1	1
Vibratory installation	36	CASL	NA	1	NA	NA	NA
Vibratory installation	48	HASE	0.001	1	<1	1	1
Vibratory installation	48	CASL	NA	1	NA	NA	NA
Impact driving	36	HASE	2.57	1	3	1	4
Impact driving	36	CASL	0.002	1	<1	1	1
Impact driving	48	HASE	0.15	1	<1	1	1
Impact driving	48	CASL	0.00005 ...	1	<1	1	1

Note: All California sea lion estimates were multiplied by a factor of 10 to account for the increased occurrence of this species due to potential for ENSO conditions.

* Using estimates for vibratory installation of 36 in (91.4 cm) steel pile as proxy for vibratory extraction of 30 in (76.2 cm) steel pile.

HASE: Harbor seal density 3.957 animals/km².

CASL: California sea lion density 0.161 animals/km².

TABLE 9—ESTIMATED TAKE BY LEVEL B HARASSMENT PER ACTIVITY

Construction activity	Pile size (in)	Condition	Species	Potential take/day	Duration of activity (day)	Estimated incidental take	Additional level B take requested (animals/day)	Total level B take
Vibratory removal	*30	Unattenuated	HASE	7.64	1–3	8–24	2	10–30
Vibratory removal	*30	Unattenuated	CASL	3.1	1–3	1–3	2	5–15
Vibratory installation	36	Unattenuated	HASE	7.64	1	8	2	10
Vibratory installation	36	Unattenuated	CASL	3.1	1	1	2	5
Vibratory installation	48	Unattenuated	HASE	7.64	1	8	2	10
Vibratory installation	48	Unattenuated	CASL	3.1	1	1	2	5
Impact driving	36	Attenuated ...	HASE	2.33	1	3	2	5
Impact driving	36	Attenuated ...	CASL	0.9	1	<1	2	2
Impact driving	48	Attenuated ...	HASE	1.94	1	2	2	4
Impact driving	48	Attenuated ...	CASL	0.8	1	<1	2	2

Note: All California sea lion estimates were multiplied by a factor of 10 to account for the increased occurrence of this species due to potential for ENSO conditions.

* Using estimates for vibratory installation of 36 in (91.4 cm) steel pile as proxy for vibratory extraction of 30 in (76.2 cm) steel pile.

HASE: Harbor seal density 3.957 animals/km².

CASL: California density 1.61 animals/km².

TABLE 10—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT PROPOSED FOR AUTHORIZATION

Species common name	Scientific name	Stock	Maximum estimated level A harassment*	Maximum estimated level B harassment**	Estimate take as a percentage of population
California sea lion***	<i>Zalophus californianus</i>	U.S.	2	25	0.011
Harbor seal	<i>Phoca vitulina richardii</i>	California	8	50	0.187

Source: NMFS SARs 2015, 2021.

* Based on 3 days of vibratory removal plus 2 days of impact driving (36 in (91.4 cm), 48 in (121.9 cm) piles only).

** Based on 3 days of vibratory removal plus 2 days of vibratory installation (36 in (91.4 cm), 48 in (121.9 cm) piles only).

*** To account for the increase in California sea lion density due to potential El Niño conditions, the daily take estimated from the density has been increased by a factor of 10 for each day that pile driving or removal occurs.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of

taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular

attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses

(latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

WETA must ensure that construction supervisors and crews, the monitoring team, and relevant WETA staff are trained prior to the start of all pile driving activities, so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood. New personnel joining during the project must be trained prior to commencing work.

Timing Restrictions

All piling activities shall be conducted between June 1 and November 30, when the likelihood of sensitive fish species being present in the work area is minimal, following U.S. Army Corps of Engineer's Proposed Additional Procedures and Criteria for Permitting Projects under a Programmatic Determination of Not Likely to Adversely Affect Select Listed Species in California (USACE, 2018). Consistent with municipal code, noise-generating construction activities would be limited to the hours between 0700 and 1900 Monday through Friday, and 0800 and 1300 on Saturdays.

Protected Species Observers

The placement of PSOs during all pile driving activities (described in the Proposed Monitoring and Reporting section) would ensure that the entire shutdown zone is visible. Should environmental conditions deteriorate such that the entire shutdown zone would not be visible (e.g., fog, heavy rain), pile driving would be delayed until the PSO is confident marine mammals within the shutdown zone could be detected.

PSOs would monitor the full shutdown zones and the Level B harassment zones to the extent practicable. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential cessation of activity should the animal enter the shutdown zone.

Pre- and Post-Activity Monitoring

Monitoring must take place from 30 minutes prior to initiation of pile driving activities (i.e., pre-clearance monitoring) through 30 minutes post-completion of pile driving. Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs would observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone would be considered cleared when a marine mammal has not been observed within the zone for a 30-minute period. If a marine mammal is observed within the shutdown zones listed in Table 11, pile driving activity would be delayed or halted. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones would commence. A determination that the shutdown zone is clear must be made during a period of good visibility (i.e., the entire shutdown zone and surrounding waters must be visible to the naked eye).

Soft-Start Procedures for Impact Driving

Soft-start procedures provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. If impact pile driving is necessary to achieve required tip elevation, WETA staff and/or contractors would be required to provide an initial set of three strikes from the hammer at reduced energy,

followed by a 30-second waiting period, then two subsequent reduced-energy strike sets. Soft-start would be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Bubble Curtain for Impact Driving

A bubble curtain must be employed during all impact pile installation of piles to interrupt the acoustic pressure and reduce impact on marine mammals. The bubble curtain must distribute air bubbles around 100 percent of the piling circumference for the full depth of the water column. The lowest bubble ring must be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring must ensure 100 percent substrate contact. No parts of the ring or other objects may prevent full substrate contact. Air flow to the bubblers must be balanced around the circumference of the pile.

Shutdown Zones

WETA must establish shutdown zones for all pile driving activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones would be based upon the Level A harassment zone for each pile size/type and driving method where applicable, as shown in Table 6. A minimum shutdown zone of 10 m would be required for all in-water construction activities to avoid physical interaction with marine mammals. For pile driving, the radii of the shutdown zones are rounded to the next largest 10 m interval in comparison to the Level A harassment zone for each activity type. If a marine mammal is observed entering or within a shutdown zone during pile driving activity, the activity must be stopped until there is visual confirmation that the animal has left the zone or the animal is not sighted for a period of 15 minutes. Proposed shutdown zones for each activity type are shown in Table 11.

All marine mammals would be monitored in the Level B harassment zones and throughout the area as far as visual monitoring can take place. If a marine mammal enters the Level B harassment zone, in-water activities would continue and PSOs would document the animal's presence within the estimated harassment zone.

TABLE 11—PROPOSED SHUTDOWN AND HARASSMENT ZONES

Method	Pile type	Pile size (in)	Shutdown zone for phocids (m)	Shutdown zone for otariids (m)	Level B harassment zone (m)
Impact, installation	Steel	36	830	60	736
Impact, installation	Steel	48	140	10	631
Vibratory, extraction *	Steel	30	40	10	4,200 W; 1,700 E
Vibratory, installation *	Steel	36	40	10	4,200 W; 1,700 E
Vibratory, installation *	Steel	48	10	10	4,200 W; 1,700 E

Note: Vibratory driving of 36 in (91.4 cm) piles used as proxy for vibratory extraction of 30 in (76.2 cm) piles.

* Constrained by bends in the Oakland Estuary and relatively shallow bathymetry near the shipping channel: 4,200 m (13,780 ft) west, 1,700 m (5,577 ft) east.

Based on our evaluation of the applicant's proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.*, presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas);

- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;

- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.*, marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

Visual Monitoring

Marine mammal monitoring must be conducted in accordance with the conditions in this section and this IHA. Marine mammal monitoring during pile driving activities would be conducted by PSOs meeting NMFS' standards and in a manner consistent with the following:

- PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods;
- At least one PSO would have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;
- Other PSOs may substitute other relevant experience, education (degree in biological science or related field), or training for prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;
- Where a team of three or more PSOs is required, a lead observer or monitoring coordinator must be designated. The lead observer must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization; and

- PSOs must be approved by NMFS prior to beginning any activity subject to the IHA.

PSOs should have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

WETA would have 1–3 PSOs stationed at the best possible vantage points in the project area to monitor during all pile driving activities. Monitoring would occur from elevated locations along the shoreline or on vessels where the entire shutdown zones are visible. PSOs would be equipped with high quality binoculars for monitoring and radios or cell phones for maintaining contact with work crews. Monitoring would be conducted 30 minutes before, during, and 30 minutes after all in-water construction activities. In addition, PSOs would record all incidents of marine mammal occurrence, regardless of distance from activity, and would document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or

remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Pre-Construction Monitoring

In addition to monitoring on days that pile removal and driving would occur, as proposed by the applicant, WETA would conduct pre-construction monitoring. Prior to initiation of in-water construction, a qualified NMFS-approved PSO will conduct monitoring of marine mammals to update existing information on species occurrence in and near the project area, their movement patterns, and their site use. This pre-construction monitoring will take place at least 5 days prior to the start of in-water construction and will cover a period of at least 1 week (with at least 5 days of actual observation over a period of 4 hours each day), 2 hours in the morning at the time that construction activities would begin and 2 hours at midday.

Reporting

WETA will provide the following reporting as necessary during active pile driving activities:

- The applicant will report any observed injury or mortality as soon as feasible and in accordance with NMFS' standard reporting guidelines. Reports will be made by phone (866-767-6114) and by email (PR.ITP.MonitoringReports@noaa.gov) and will include the following:
 - Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
 - Species identification (if known) or description of the animal(s) involved;
 - Condition of the animal(s) (including carcass condition if the animal is dead);
 - Observed behaviors of the animal(s), if alive;
 - If available, photographs or video footage of the animal(s); and,
 - General circumstances under which the animal was discovered.

• An annual report summarizing the prior year's activities will be provided that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring, estimates the number of listed marine mammals that may have been incidentally taken during project pile driving, and provides an interpretation of the results and effectiveness of all monitoring tasks. The annual draft report will be provided no later than 90 days following completion of construction activities. Any recommendations made by NMFS will

be addressed in the final report, due after the IHA expires and including a summary of all monitoring activities, prior to acceptance by NMFS. Final reports will follow a standardized format for PSO reporting from activities requiring marine mammal mitigation and monitoring.

- All PSOs will use a standardized data entry format (see Appendix B of the IHA application).

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to both California sea lions and harbor seals, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity.

Pile driving and removal activities have the potential to disturb or displace marine mammals. Specifically, the

project activities may result in take, in the form of Level A and Level B harassment from underwater sounds generated from pile driving and removal. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway.

The proposed takes by Level A and Level B harassment would be due to potential behavioral disturbance, TTS, and PTS. No mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. The potential for harassment is minimized through the construction method and the implementation of the planned mitigation measures (see Proposed Mitigation section).

The Level A harassment zones identified in Table 6 are based upon an animal exposed to impact pile driving multiple piles per day. Considering duration of impact driving each pile (up to 20 minutes) and breaks between pile installations (to reset equipment and move pile into place), this means an animal would have to remain within the area estimated to be ensonified above the Level A harassment threshold for multiple hours. This is highly unlikely given marine mammal movement throughout the area. If an animal was exposed to accumulated sound energy, the resulting PTS would likely be small (*e.g.*, PTS onset) at lower frequencies where pile driving energy is concentrated, and unlikely to result in impacts to individual fitness, reproduction, or survival.

The nature of the pile driving project precludes the likelihood of serious injury or mortality. For all species and stocks, take would occur within a limited, confined area (north-central San Francisco Bay including Richardson's Bay) of the stock's range. Level A and Level B harassment will be reduced to the level of least practicable adverse impact through use of mitigation measures described herein. Further, the amount of take proposed to be authorized is extremely small when compared to stock abundance.

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities per day and that pile driving and removal would occur across 6 consecutive days, any

harassment would be temporary. There are no other areas or times of known biological importance for any of the affected species.

In addition, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the stocks' ability to recover. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- The specified activities and associated ensonified areas are very small relative to the overall habitat ranges of both species;
- The project area does not overlap with known BIAs or ESA-designated critical habitat;
- The lack of anticipated significant or long-term effects to marine mammal habitat;
- The presumed efficacy of the mitigation measures in reducing the effects of the specified activity; and,
- Monitoring reports from similar work in San Francisco Bay have documented little to no effect on individuals of the same species impacted by the specified activities (AECOM, 2022; AECOM, 2023).

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most

appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS has authorized is below one-third of the estimated stock abundances for all seven stocks (see Table 9). For both stocks, the proposed take of individuals is less than 1 percent of the abundance of the affected stock. This is likely a conservative estimate because it assumes all takes are of different individual animals, which is likely not the case. Some individuals may return multiple times in a day, but PSOs would count them as separate takes if they cannot be individually identified.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that

formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to WETA for conducting pile removal and driving in the Oakland Inner Harbor at Alameda, California, for one year from the date of issuance, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed construction project. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, one-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA); and

- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.*, reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: June 26, 2023.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD006]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys in the New York Bight

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an IHA to Community Offshore Wind, LLC (COSW) to incidentally harass marine mammals during marine site characterization surveys in coastal waters off of New Jersey and New York in the New York Bight.

DATES: This authorization is effective from July 1, 2023, through June 30, 2024.

FOR FURTHER INFORMATION CONTACT:

Alyssa Clevens, Office of Protected Resources, NMFS, (301) 427-8401.

Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable>. In case of

problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental harassment authorization (IHA) is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as “mitigation”); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On November 17, 2022, NMFS received a request from COSW for an IHA to take marine mammals incidental to conducting marine site characterization surveys in coastal waters off of New Jersey and New York in the New York Bight, specifically within the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS) Lease Area OCS-A 0539 (Lease Area) and associated Export Cable Route survey area (ECR Area). Following NMFS’ review of the application, COSW submitted a revised request on February 27, 2023. NMFS deemed the application adequate and complete on March 1, 2023. COSW’s request is for take of

small numbers of 15 species (16 stocks) of marine mammals by Level B harassment only. Neither COSW nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Specified Activity

Overview

COSW plans to conduct marine site characterization surveys, including high-resolution geophysical (HRG) surveys, in coastal waters off of New Jersey and New York in the New York Bight, specifically within BOEM Lease Area OCS-A 0539 and associated ECR Area, collectively considered the Survey Area.

The planned marine site characterization surveys are designed to obtain data sufficient to meet BOEM guidelines for providing geophysical, geotechnical, and geohazard information for site assessment plan surveys and/or construction and operations plan development. The objective of the surveys is to support the site characterization, siting, and engineering design of offshore wind project facilities including wind turbine generators, offshore substations, and submarine cables within the Survey Area. Up to three vessels may conduct survey efforts concurrently. Underwater sound resulting from COSW’s marine site characterization survey activities, specifically HRG surveys, have the potential to result in incidental take of marine mammals in the form of Level B harassment.

Dates and Duration

The surveys are planned to begin as soon as practicable and estimated to require 293 survey days within a single year across a maximum of three vessels operating concurrently, which includes up to two vessels operating offshore (>20 meters (m) depth) and one vessel operating nearshore (<20 m depth). The survey days will occur any month throughout the year as the exact timing of the surveys during the year is not certain. A “survey day” is defined as a 24-hour (hr) activity period in which active acoustic sound sources are used offshore and a 12-hr activity period when a vessel is operating nearshore. It is expected that each offshore vessel would cover approximately 170 kilometers (km) of trackline per day surveyed at a speed of approximately 3.8 knots (kn; 7.04 km/h), based on COSW’s expectations regarding data acquisition efficiency. There is up to 30,467 km of trackline survey effort planned; a maximum trackline length of 28,290 km is planned for the Lease Area

and 2,177 km for the ECR Area. The IHA would be effective for 1 year from the date of issuance.

Specific Geographic Region

COSW's survey activities will occur in coastal waters off of New Jersey and New York in the New York Bight, specifically within BOEM Lease Area

OCS-A 0539 and associated ECR Area (Figures 1, 2). The Survey Area (14,759 km²) includes both the Lease Area (859 km²; 30–51 m depth) and ECR Area (13,900 km²; 3–65 m depth).

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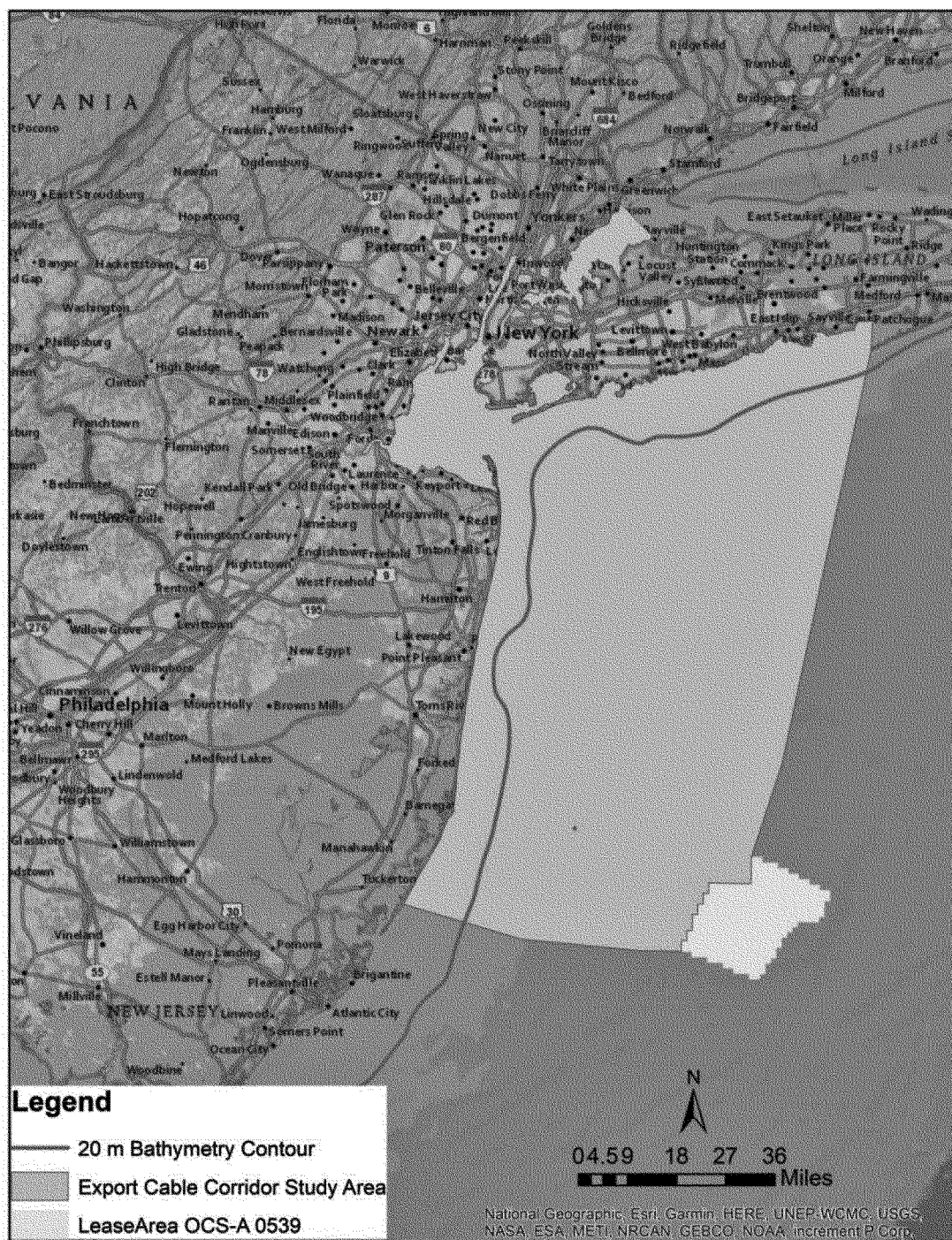


Figure 1 – Survey Area

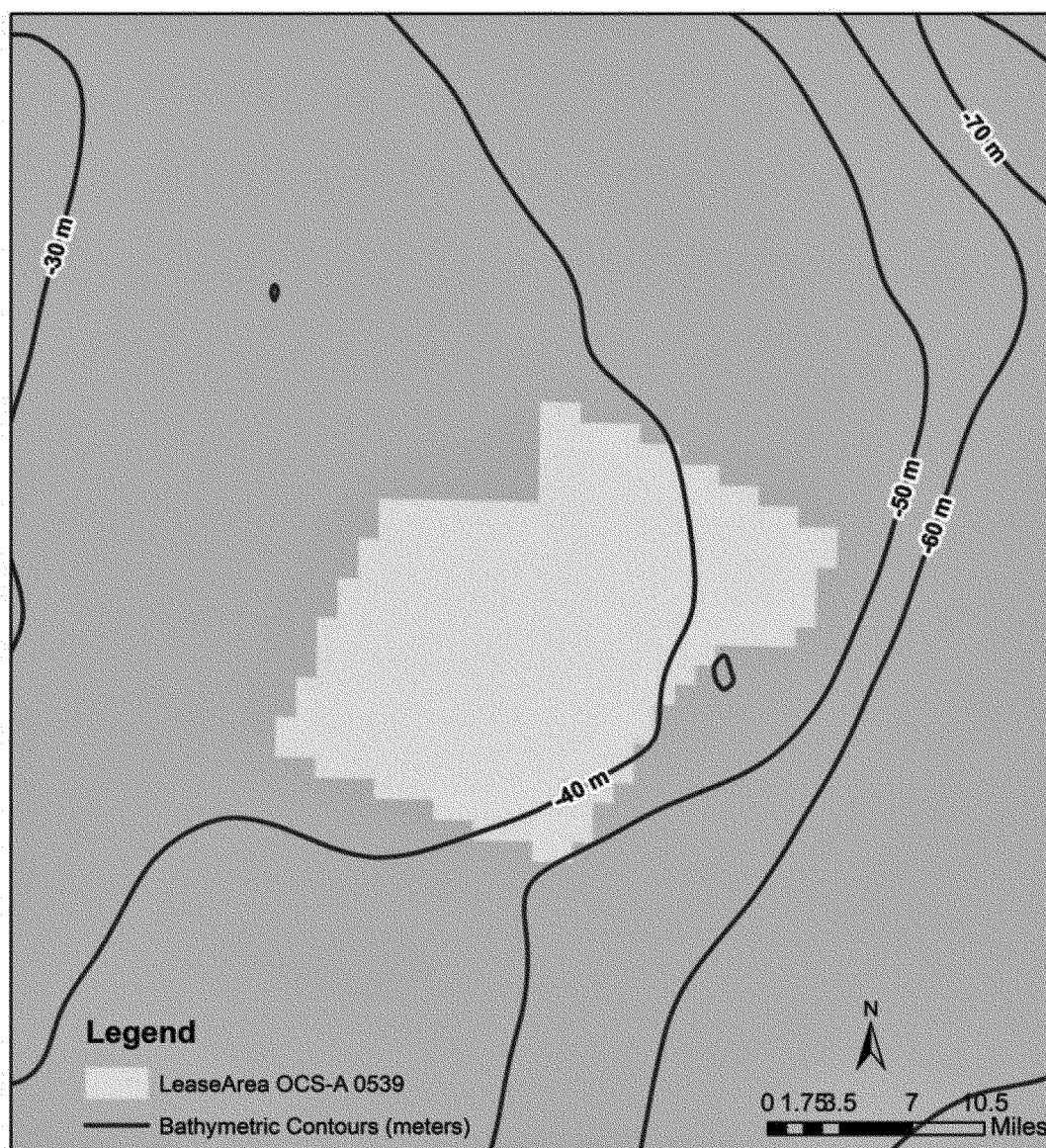


Figure 2 – Lease Area with Bathymetric Contours Showing Water Depth

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Detailed Description of the Specified Activity

COSW's marine site characterization surveys within the Survey Area include geotechnical and geophysical surveys, including depth sounding to determine water depth, site bathymetry, and general seafloor topography using a multibeam echosounder (MBES); and medium penetration sub-bottom profilers (SBP; sparker) in a single (2-dimensional (2D)) or triple (3-dimensional (3D)) configuration.

Within the Lease Area and across a 500-m buffer around the Lease Area (30–51 m depth), COSW will acquire MBES data and ultra-high resolution seismic (UHRS) data in either 2D (single

sparker) or 3D (triple sparker) scenario. Within the ECR Area (3–65 m depth), the survey will consist of MBES and UHRS data collection within up to 900-m wide corridors. A centerline of UHRS data will be collected with 500-m tielines. COSW would acquire MBES data at a line spacing controlled by water depth to meet coverage and resolution requirements. MBES are used to determine water depths and general bottom topography. The MBES have operating frequencies greater than 180 kilohertz (kHz) and are therefore outside the general hearing range of marine mammals. NMFS does not expect MBES survey activities to present a reasonably anticipated risk of causing incidental take of marine mammals, so these

activities are not discussed further in this notice.

COSW plans two scenarios: the 2D scenario and the 3D scenario. The total survey trackline length differs between the 2D and 3D scenarios but both scenarios include a maximum of two concurrently-operating vessels in the Lease Area with the potential for a third vessel operating concurrently in the ECR Area. For the 2D scenario, a trackline length of 5,370 km (1,515 km² ensonified area) is planned for the Lease Area and 2,177 km (615 km² ensonified area) for the ECR Area. Each vessel will operate one sparker in the 2D scenario. Under the 3D scenario, a trackline length of 28,290 km (8,923 km² ensonified area) is planned for the Lease Area and 2,177 km (688 km² ensonified

area) for the ECR Area. Each vessel will operate three sparkers in the 3D scenario. The ECR Area trackline length remains the same across both scenarios. Only one vessel will operate in nearshore waters <20 m depth and will adhere to a 12-hr survey day.

The only acoustic sources planned for use during COSW's HRG survey activities with the potential to cause incidental take of marine mammals are the sparkers. There are two sparker systems planned for use: Applied Acoustics Dura-Spark UHD 400+400 Seismic Sound Source (400 tip/300–1,000 joules (J)) and the Geo-Source 200–400 Marine Multi-Tip Sparker System (400 tip/300–1,000 J).

A detailed description of COSW's planned HRG surveys is provided in the **Federal Register** notice for the proposed IHA (88 FR 24574, April 21, 2023). Since that time, no changes have been made to the planned HRG survey activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the detailed description of the specified activity.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to COSW was published in the **Federal Register** on April 21, 2023 (88 FR 24574). That notice described, in detail, COSW's proposed activities, the marine mammal species that may be affected by the activities, and the anticipated effects on marine mammals. In that notice, we requested public input on the request for authorization described therein, our analyses, the proposed authorization, and any other aspect of the notice of proposed IHA, and requested that interested persons submit relevant information, suggestions, and comments. This proposed notice was available for a 30-day public comment period.

NMFS received 13 comment letters. Two of these comment letters were from non-governmental organizations: the Responsible Offshore Development Alliance (RODA) and Clean Ocean Action (COA), and one was from an elected local governmental official (Mayor of Borough of Seaside Park, New Jersey; Seaside Park). The remaining ten comments were from private citizens.

All comments from private citizens expressed general opposition to issuance of the IHA or to the underlying associated activities. We reiterate here that NMFS' action concerns only the authorization of marine mammal take incidental to the planned surveys—NMFS' authority under the MMPA does not extend to the surveys themselves, or to wind energy development more

generally. Several commenters suggested, without evidence, that issuance of the proposed IHA could result in the death of whales. We reiterate here that no mortality is anticipated or authorized. Many of the comments requested that NMFS not issue any IHAs related to wind energy development and/or expressed opposition for wind energy development generally without providing information relevant to NMFS' decision. We do not specifically address comments expressing general opposition to activities related to wind energy development or respond to comments that are out of scope of the proposed IHA (88 FR 24574), such as comments on other Federal agency processes and activities not planned under this IHA.

All substantive comments and NMFS' responses are provided below, and all comment letters are available online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-community-offshore-wind-llc-marine-site-characterization>. Please review the comment letters for full details regarding the comments and associated rationale.

Comment: Multiple commenters expressed concern that negative impacts to the local fishing industry and coastal communities as a result of a potentially adverse impact to marine mammals (e.g., vessel strike resulting in death or severe injury) were not mentioned or evaluated in this IHA. RODA specifically noted concern regarding existing fishery restrictions as a result of other North Atlantic right whale (NARW) protections.

Response: Neither the MMPA nor our implementing regulations require NMFS to analyze impacts to other industries (e.g., fisheries) or coastal communities from issuance of an incidental take authorization (ITA). Moreover, NMFS has determined that no serious injury or mortality is anticipated to result from COSW's specified activities and as discussed in the Negligible Impact Analysis and Determination section in this notice, only low-level behavioral harassment is expected for any affected species. For NARW in particular, it is considered unlikely, as a result of the required precautionary shutdown zone (i.e., 500 m versus the estimated maximum Level B harassment zone of 158 m), that the authorized take would occur at all.

Comment: Multiple commenters expressed concern about an alleged lack of adequate analysis of cumulative impacts to marine mammals.

Response: Neither the MMPA nor NMFS' codified implementing

regulations call for consideration of other unrelated activities and their impacts on marine mammal populations. The preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989) states in response to comments that the impacts from other past and ongoing anthropogenic activities are to be incorporated into the negligible impact analysis via their impacts on the baseline. Consistent with that direction, NMFS has factored into its negligible impact analysis the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline, e.g., as reflected in the density, distribution and status of the species, population size and growth rate, and other relevant stressors. The 1989 final rule for the MMPA implementing regulations also addressed public comments regarding cumulative effects from future, unrelated activities. There NMFS stated that such effects are not considered in making findings under MMPA section 101(a)(5) concerning negligible impact. In this case, this IHA, as well as other IHAs currently in effect or proposed within the specified geographic region, are appropriately considered an unrelated activity relative to the others. The IHAs are unrelated in the sense that they are discrete actions under section 101(a)(5)(D), issued to discrete applicants.

Section 101(a)(5)(D) of the MMPA requires NMFS to make a determination that the take incidental to a "specified activity" will have a negligible impact on the affected species or stocks of marine mammals. NMFS' implementing regulations 50 CFR 216.104(a)(1) require applicants to include in their request a detailed description of the specified activity or class of activities that can be expected to result in incidental taking of marine mammals. Thus, the "specified activity" for which incidental take coverage is being sought under section 101(a)(5)(D) is generally defined and described by the applicant. Here, COSW was the applicant for the IHA, and we are responding to the specified activity as described in that application and making the necessary findings on that basis.

Through the response to public comments in the 1989 implementing regulations, NMFS also indicated (1) that we would consider cumulative effects that are reasonably foreseeable when preparing a NEPA analysis, and (2) that reasonably foreseeable cumulative effects would also be considered under section 7 of the Endangered Species Act (ESA) for ESA-listed species, as appropriate. Accordingly, NMFS has written

Environmental Assessments (EA) that addressed cumulative impacts related to substantially similar activities in similar locations (*e.g.*, the 2019 Avangrid EA for survey activities offshore North Carolina and Virginia; the 2017 Ocean Wind, LLC EA for site characterization surveys off New Jersey; and the 2018 Deepwater Wind EA for survey activities offshore Delaware, Massachusetts, and Rhode Island). Cumulative impacts regarding issuance of IHAs for site characterization survey activities such as those planned by COSW have been adequately addressed under NEPA in prior environmental analyses that support NMFS' determination that this action is appropriately categorically excluded from further NEPA analysis. NMFS independently evaluated the use of a categorical exclusion (CE) for issuance of COSW's IHA, which included consideration of extraordinary circumstances.

Separately, the cumulative effects of substantially similar activities in the northwest Atlantic Ocean have been analyzed in the past under section 7 of the ESA when NMFS has engaged in formal intra-agency consultation, such as the 2013 programmatic Biological Opinion for BOEM Lease and Site Assessment Rhode Island, Massachusetts, New York, and New Jersey Wind Energy Areas (<https://repository.library.noaa.gov/view/noaa/29291>). Analyzed activities include those for which NMFS issued previous IHAs (82 FR 31562, July 7, 2017; 83 FR 28808, June 21, 2018; 83 FR 36539, July 30, 2018; and 86 FR 26465, May 10, 2021), which are similar to those planned by COSW under this current IHA request. This Biological Opinion (BiOp) determined that NMFS' issuance of IHAs for site characterization survey activities associated with leasing, individually and cumulatively, are not likely to adversely affect listed marine mammals. NMFS notes that, while issuance of this IHA is covered under a different consultation, this BiOp remains valid.

Comment: Multiple commenters urged NMFS to deny the proposed project and/or postpone any offshore wind (OSW) activities until NMFS determines effects of all OSW activities on marine mammals in the region and determines that the recent whale deaths are not related to OSW activities. Similarly, some commenters provided general concerns regarding recent whale stranding events on the Atlantic Coast, including speculation that the strandings may be related to wind energy development-related activities. However, the commenters did not

provide any specific information supporting these concerns.

Response: NMFS authorizes take of marine mammals incidental to marine site characterization surveys but does not authorize the surveys themselves. Therefore, while NMFS has the authority to modify, suspend, or revoke an IHA if the IHA holder fails to abide by the conditions prescribed therein (including, but not limited to, failure to comply with monitoring or reporting requirements), or if NMFS determines that (1) the authorized taking is having or is likely to have more than a negligible impact on the species or stocks of affected marine mammals, or (2) the prescribed measures are likely not or are not effecting the least practicable adverse impact on the affected species or stocks and their habitat, it is not within NMFS' jurisdiction to impose a moratorium on offshore wind development or to require surveys to cease on the basis of unsupported speculation.

NMFS reiterates that there is no evidence that noise resulting from offshore wind development-related site characterization surveys could potentially cause marine mammal stranding, and there is no evidence linking recent large whale mortalities and currently ongoing surveys. The commenters offer no such evidence. NMFS will continue to gather data to help us determine the cause of death for these stranded whales. We note the Marine Mammal Commission's recent statement: "There continues to be no evidence to link these large whale strandings to offshore wind energy development, including no evidence to link them to sound emitted during wind development-related site characterization surveys, known as HRG surveys. Although HRG surveys have been occurring off New England and the mid-Atlantic coast, HRG devices have never been implicated or causatively-associated with baleen whale strandings." (Marine Mammal Commission Newsletter, Spring 2023).

There is an ongoing Unusual Mortality Event (UME) for humpback whales along the Atlantic coast from Maine to Florida, which includes animals stranded since 2016. Partial or full necropsy examinations were conducted on approximately half of the whales. Necropsies were not conducted on other carcasses because they were too decomposed, not brought to land, or stranded on protected lands (*e.g.*, national and state parks) with limited or no access. Of the whales examined (roughly 90), about 40 percent had evidence of human interaction, either ship strike or entanglement. Vessel

strikes and entanglement in fishing gear are the greatest human threats to large whales. The remaining 50 necropsied whales either had an undetermined cause of death (due to a limited examination or decomposition of the carcass), or had other causes of death including parasite-caused organ damage and starvation.

As discussed herein, HRG sources may behaviorally disturb marine mammals (*e.g.*, avoidance of the immediate area). These HRG surveys are very different from seismic airguns used in oil and gas surveys or tactical military sonar. They produce much smaller impact zones because, in general, they have lower source levels and produce output at higher frequencies. The area within which HRG sources might behaviorally disturb a marine mammal is orders of magnitude smaller than the impact areas for seismic airguns or military sonar. Any marine mammal exposure would be at significantly lower levels and shorter duration, which is associated with less severe impacts to marine mammals.

Comment: Several commenters expressed a concern that the proposed IHA and its associated specified activities would lead to mortality (death) of marine mammals.

Response: NMFS emphasizes that there is no credible scientific evidence available suggesting that mortality and/or serious injury is a potential outcome of the planned survey activity. Additionally, NMFS cannot authorize mortality or serious injury via an IHA, and such taking is prohibited under Condition 3(c) of the IHA and may result in modification, suspension, or revocation of the IHA. NMFS notes there has never been a report of any serious injuries or mortalities of a marine mammal associated with site characterization surveys.

The best available science indicates that Level B harassment, or disruption of behavioral patterns, may occur as a result of COSW's specified activities. We also refer to the Greater Atlantic Regional Fisheries Office (GARFO) 2021 Programmatic Consultation, which finds that these survey activities are in general not likely to adversely affect ESA-listed marine mammal species (*i.e.*, GARFO's analysis conducted pursuant to the ESA finds that marine mammals are not likely to be taken at all (as that term is defined under the ESA), much less be taken by serious injury or mortality). That document is found at <https://www.fisheries.noaa.gov/new-england-mid-atlantic/consultations/section-7-take-reporting-programmatics-greater-atlantic#offshore-wind-site->

assessment-and-site-characterization-activities-programmatic-consultation.

Comment: COA states that there is no legal authority for permitting offshore geotechnical and geophysical survey activities under BOEM, based on text from the proposed BOEM Renewable Energy Modernization proposed rule (88 FR 5968, January 30, 2023; 88 FR 19578, April 3, 2023). They further state that this has allowed for no oversight with regards to surveys off New Jersey and New York and that they do not understand how BOEM can make assertions without regulations/guidance for HRG survey work.

Response: NMFS' statutory authority for this particular action is limited to authorizing incidental take of marine mammals. NMFS respectfully refers the commenter to BOEM, the agency with responsibility for managing development of U.S. Outer Continental Shelf energy and mineral resources in an environmentally and economically responsible way.

Comment: RODA expressed concern regarding increased vessel traffic associated with OSW development generally and asserted that vessel speed restrictions are not "fully mandated or enforced for OSW vessels."

Response: NMFS appreciates the commenter's concern regarding the potential for an overall increase in vessel traffic at the regional scale. However, we also note that concerns regarding the potential impacts of wind energy development in general are outside the scope of this specific action (*i.e.*, issuance of an IHA associated with a specific HRG survey). NMFS takes seriously the risk of vessel strike and has prescribed measures to avoid the potential for vessel strike, despite a very low likelihood, to the extent practicable. The full list of mitigation measures can be found in Condition 4(m) of the IHA and in the Mitigation section of this notice. In addition, vessels towing survey gear travel at very slow speeds (4–5 kn) (reducing the already low likelihood of strike), and vessels associated with the survey activity will add a discountable amount of vessel traffic to the specific geographic region. We have determined that the IHA's vessel strike avoidance measures are sufficient to ensure the least practicable adverse impact on species or stocks and their habitat. Furthermore, NMFS is unaware of any vessel strikes related to marine site characterization surveys.

RODA's reference to vessel speed restrictions being "not fully mandated" is unclear. NMFS refers again to its required vessel strike avoidance measures (see Condition 4(m)(ii) of the issued IHA), which requires that all

vessels, regardless of size, observe a 10-knot speed restriction in SMAs, DMAs, and Slow Zones. Similarly, RODA does not provide a rationale for its suggestion that vessel speed restrictions are not enforced. We note that NMFS maintains an Enforcement Hotline for members of the public to report violations of vessel speed restrictions. Further, the IHA states that the IHA may be modified, suspended, or revoked if the holder fails to abide by the conditions prescribed therein.

Comment: Several commenters expressed concern about the use of multiple vessels concurrently performing the survey work.

Response: NMFS appreciates the commenters' concerns but notes that no evidence is provided to substantiate this concern. NMFS believes that the authorized take numbers adequately account for the potential take that may result from the proposed survey work, inclusive of the concurrent use of surveying vessels.

Comment: One commenter stated that the review process for this IHA was too rapid and NMFS' due diligence was lacking.

Response: Section 101(a)(5)(D)(iii) of the MMPA and NMFS implementing regulations (50 CFR 216.104) specify the procedural requirements for IHA issuance. Additionally, NMFS' internal ITA application and review process includes numerous steps to ensure due diligence occurs for all ITA requests. In this case, NMFS received COSW's initial application on November 17, 2022, and completed several rounds of agency review and analysis before NMFS considered the application adequate and complete on March 1, 2023. NMFS drafted the **Federal Register** notice of the proposed IHA and proposed IHA, which went through additional rounds of internal review. The notice and proposed IHA were published in the **Federal Register** on April 21, 2023 (88 FR 24574) and was open for a 30-day comment period (*i.e.*, through May 22, 2023). NMFS reviewed all within-scope comments received for consideration in the final decisional process.

More information on the authorization steps and timelines can be found at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act>.

Comment: Commenters stated that NMFS was not utilizing the best available science when assessing impacts to marine mammals.

Response: NMFS relied upon the best scientific evidence available, including, but not limited to, the draft 2022 Stock

Assessment Reports (SAR), scientific literature, and Duke University's density model (Roberts *et al.*, 2022), in analyzing the impacts of COSW's specified activities on marine mammals. While commenters suggest generally that NMFS consider the best scientific evidence available, none of the commenters provided additional scientific information for NMFS to consider.

Comment: RODA stated that, to their knowledge, there are no resources easily accessible to the public to understand what authorizations are required for each of these activities (pre-construction surveys, construction, operations, monitoring surveys, *etc.*). RODA recommends that NMFS improve the transparency of this process and move away from what it refers to as a "segmented phase-by-phase and project-by-project approach to IHAs." RODA also requested a "comprehensive list/table of all Level A and Level B takes under currently approved authorizations per project, as well as Level A and Level B takes per project being requested in all authorization applications currently under review."

Response: The MMPA and its implementing regulations allow upon request, the incidental take of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographic region. NMFS authorizes the requested incidental take of marine mammals if it finds that the taking would be of small numbers, have no more than a "negligible impact" on the marine mammal species or stock, and not have an "unmitigable adverse impact" on the availability of the species or stock for subsistence use. NMFS refers RODA to its website for more information on the marine mammal incidental take authorization process and timelines: <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act>.

NMFS emphasizes that an IHA does not authorize the activity itself but authorizes the take of marine mammals incidental to the "specified activity" for which incidental take coverage is being sought. In this case, NMFS is responding to COSW's request to incidentally take marine mammals while engaged in marine site characterization surveys and determining whether the necessary findings can be made based on COSW's application. The authorization of COSW's survey activities is not within NMFS' jurisdiction. NMFS refers RODA to BOEM's website: <https://www.boem.gov/renewable-energy>.

A list of all proposed and issued IHAs for renewable energy activities, such as COSW's marine site characterization surveys, including the requested, proposed, and/or authorized take is available on the agency website at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable>.

Comment: RODA expressed concern regarding the potential for increased uncertainty in estimates of marine mammal abundance resulting from wind turbine presence during aerial surveys and potential effects of NMFS' ability to continue using current aerial survey methods to fulfill its mission of precisely and accurately assessing protected species.

Response: NMFS has determined that OSW development projects may impact several Northeast Fisheries Science Center (NEFSC) surveys, including aerial surveys for protected species. NEFSC has developed a Federal survey mitigation program to mitigate the impacts to these surveys and is in the early stages of implementing this program. However, this impact is outside the scope of analysis related to the authorization of take incidental to COSW's specified activity under the MMPA.

Comment: RODA commented that additional clarification should be added to the IHA that explicitly states if weather or other conditions that limit the range of observation of shutdown zones will be initiated. RODA and COA also questioned the feasibility of the shutdown mitigation requirements in real-world conditions and what would occur if the authorized take levels were exceeded. COA stated concerns on the required mitigation measures, assessing the effectiveness of the mitigation measures, and reporting the use of the mitigation measures in real-time.

Response: In regards to a scenario where COSW exceeds their authorized take levels, any further take would be unauthorized and, therefore, prohibited under the MMPA. All mitigation measures stated in this notice and in the issued IHA are considered feasible. NMFS works with each ITA applicant, including COSW, to ensure that project-specific mitigation measures are possible in real-world conditions. This includes shutdown zones when there is reduced visibility. As stated in the IHA condition 5(d), COSW must ensure certain equipment is provided to protected species observers (PSOs), such as thermal (infrared) cameras, to allow PSOs to adequately complete their duties, including in reduced-visibility conditions. NMFS does not agree that

additional wording is necessary within the IHA to further describe the requirement and implementation of shutdown zones. If NMFS determines during the effective period of the IHA that the prescribed measures are likely not or are not effecting the least practicable adverse impact on the affected species or stocks and their habitat, NMFS may modify, suspend, or revoke the IHA. NMFS disagrees that the IHA's mitigation measures are insufficient.

NMFS reviews required reporting (see Monitoring and Reporting) and uses the information to evaluate the mitigation measure effectiveness. Additionally, the mitigation measures included in COSW's IHA are not unique, and data from prior IHAs support the effectiveness of these mitigation measures. NMFS finds the level of reporting currently required is sufficient for managing the issued IHA and monitoring the affected stocks of marine mammals.

Comment: Some comments objected to NMFS' "small numbers" determination for the numbers of marine mammals taken by Level B harassment under COSW's planned activities.

Response: NMFS disagrees with the commenters' arguments on the topic of small numbers. Although there is limited legislative history available to guide NMFS and an apparent lack of biological underpinning to the concept, we have worked to develop a reasoned approach to small numbers. NMFS explains the concept of "small numbers" in recognition that there could also be quantities of individuals taken that would correspond with "medium" and "large" numbers. As such, NMFS considers that one-third of the most appropriate population abundance number—as compared with the assumed number of individuals taken—is an appropriate limit with regard to "small numbers." This relative approach is consistent with the statement from the legislative history that "[small numbers] is not capable of being expressed in absolute numerical limits" (H.R. Rep. No. 97-228, at 19 (September 16, 1981)), and relevant case law (*Center for Biological Diversity v. Salazar*, 695 F.3d 893, 907 (9th Cir. 2012) (holding that the U.S. Fish and Wildlife Service reasonably interpreted "small numbers" by analyzing take in relative or proportional terms)). NMFS has made the necessary small numbers finding for all affected species and stocks in this case.

Comment: Several commenters expressed interest in understanding the outcome if the number of actual takes

exceed the number authorized during construction of an offshore wind project (*i.e.*, would the project be stopped mid-construction or operation), and how offshore wind developers will be held accountable for impacts to protected species such that impacts are not inadvertently assigned to fishermen, should they occur. Lastly, RODA maintains that the OSW industry must be accountable for incidental takes from construction and operations separately from the take authorizations for managed commercial fish stocks.

Response: NMFS reiterates that this IHA authorizes incidental take of marine mammals during marine site characterization survey activities and not offshore wind project construction and operation activities. Therefore, these comments are outside the scope of the proposed IHA. Fishing impacts generally center on entanglement in fishing gear, which is a very acute, visible, and severe impact. In contrast, the impacts incidental to COSW's site characterization survey activities are primarily acoustic in nature resulting in behavioral disturbance. Because of the difference in potential impacts (*i.e.*, physical versus auditory), any impacts resulting from COSW's survey activities would not be assigned to fishermen. The impacts of commercial fisheries on marine mammals and incidental take for said fishing activities are managed separately from those of non-commercial fishing activities such as offshore wind site characterization surveys, under MMPA section 118.

Comment: COA expressed concern regarding ocean noise and the interference it has on communication between whales.

Response: NMFS has carefully reviewed the best available scientific information in assessing impacts to marine mammals and determined that the surveys have the potential to impact marine mammals through behavioral effects and auditory masking. NMFS agrees that noise pollution in marine waters is an issue and is affecting marine mammals, including their ability to communicate when noise reaches certain thresholds. However, NMFS does not expect that the generally short-term, intermittent, and transitory marine site characterization survey activities planned by COSW will create conditions of acute or chronic acoustic exposure leading to long-term physiological impacts in marine mammals. NMFS' prescribed mitigation measures are expected to further reduce the duration and intensity of acoustic exposure, while limiting the potential severity of any possible behavioral disruption. NMFS has determined

COSW's activities will not result in injury or mortality (death) of any marine mammal species.

Changes From the Proposed IHA to Final IHA

One change was made from the proposed IHA as a result of consultation with GARFO: an addition to the Monitoring and Reporting section specifying requirements relating to the use of a "trained lookout" in lieu of a PSO during required breaks for the approved PSO on duty on space-limited nearshore vessels.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, incorporated here by reference, instead

of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' SARs (www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments) and more general information about these species (e.g., physical and behavioral descriptions) may be found on NMFS' website (<https://www.fisheries.noaa.gov/find-species>).

Table 1 lists all species or stocks for which take is authorized for this activity, and summarizes information related to the species or stock, including regulatory status under the MMPA and ESA, and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is authorized

here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All MMPA managed stocks in this region are assessed in NMFS' U.S. Atlantic and Gulf of Mexico SARs. All values presented in Table 1 are the most recent available at the time of publication (including from the draft 2022 SARs) and are available online at: www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.

TABLE 1—SPECIES AND STOCKS LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES ¹

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Artiodactyla—Infraorder Cetacea—Mysticeti (baleen whales)						
Family Balaenidae: North Atlantic right whale	<i>Eubalaena glacialis</i>	Western North Atlantic	E/D; Y	338 (0; 332; 2020)	0.7	8.1
Family Balaenopteridae (rorquals):						
Fin whale	<i>Balaenoptera physalus</i>	Western North Atlantic	E/D; Y	6,802 (0.24; 5,573; 2016)	11	1.8
Humpback whale	<i>Megaptera novaeangliae</i>	Gulf of Maine	-/-; Y	1,396 (0; 1,380; 2016)	22	12.15
Minke whale	<i>Balaenoptera acutrostrata</i>	Canadian East Coastal	-/-; N	21,968 (0.31; 17,002; 2016).	170	10.6
Sei whale	<i>Balaenoptera borealis</i>	Nova Scotia	E/D; Y	6,292 (1.02; 3,098; 2016)	6.2	0.8
Odontoceti (toothed whales, dolphins, and porpoises)						
Family Physeteridae: Sperm whale	<i>Physeter macrocephalus</i>	North Atlantic	E/D; Y	4,349 (0.28; 3,451; 2016)	3.9	0
Family Delphinidae:						
Atlantic spotted dolphin	<i>Stenella frontalis</i>	Western North Atlantic	-/-; N	39,921 (0.27; 32,032; 2016).	320	0
Atlantic white-sided dolphin.	<i>Lagenorhynchus acutus</i>	Western North Atlantic	-/-; N	93,233 (0.71; 54,443; 2016).	544	27
Bottlenose dolphin	<i>Tursiops truncatus</i>	Western North Atlantic, Off-shore.	-/-; N	62,851 (0.23; 51,914; 2016).	519	28
Bottlenose dolphin	<i>Tursiops truncatus</i>	Western North Atlantic, Northern Migratory Coastal.	-/D; Y	6,639 (0.41; 4,759; 2016)	48	12.2–21.5
Long-finned pilot whale	<i>Globicephala melas</i>	Western North Atlantic	-/-; N	39,215 (0.3; 30,627; 2016)	306	9
Risso's dolphin	<i>Grampus griseus</i>	Western North Atlantic	-/-; N	35,215 (0.19; 30,051; 2016).	301	34
Common dolphin	<i>Delphinus delphis</i>	Western North Atlantic	-/-; N	172,974 (0.21; 145,216; 2016).	1,452	390
Family Phocoenidae (porpoises):						
Harbor porpoise	<i>Phocoena phocoena</i>	Gulf of Maine/Bay of Fundy ..	-/-; N	95,543 (0.31; 74,034; 2016).	851	164
Order Carnivora—Pinnipedia						
Family Phocidae (earless seals):						
Gray seal ⁵	<i>Halichoerus grypus</i>	Western North Atlantic	-/-; N	27,300 (0.22; 22,785; 2016).	1,389	4,453

TABLE 1—SPECIES AND STOCKS LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES¹—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Harbor seal	<i>Phoca vitulina</i>	Western North Atlantic	-/-; N	61,336 (0.08; 57,637; 2018).	1,729	329

¹ Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/>; Committee on Taxonomy (2022)).

² ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

³ NMFS marine mammal stock assessment reports online at: www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

⁴ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (M/SI; e.g., commercial fisheries, vessel strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

⁵ NMFS's stock abundance estimate (and associated PBR value) applies to the U.S. population only. Total stock abundance (including animals in Canada) is approximately 451,600. The annual M/SI given is for the total stock.

A detailed description of the species likely to be affected by this project, including brief introductions to the species and relevant stocks, population trends and threats, and local occurrence, were provided in the **Federal Register** notice for the proposed IHA (88 FR 24574, April 21, 2023). Since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to the NMFS website (<https://www.fisheries.noaa.gov/find-species>) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (e.g., Richardson *et al.*, 2005, Wartzok and Ketten, 1999, Au and Hastings, 2008). To reflect this, Southall *et al.* (2007), Southall *et al.* (2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or

estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.*, low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65-decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS (NMFS, 2018)

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on approximately 65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006, Kastelein *et al.*, 2009, Reichmuth *et al.*, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

A description of the potential effects of the specified activities on marine mammals and their habitat can be found in the **Federal Register** notice for the proposed IHA (88 FR 24574, April 21, 2023). There is no new information on the potential effects of the specified activities on marine mammals. Therefore, that information is not repeated here; please refer to the

Federal Register notice (88 FR 24574, April 21, 2023).

Estimated Take

This section provides an estimate of the number of incidental takes authorized through the IHA, which informs both NMFS' "small numbers" and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities

not pertinent here, section 3(18) of the MMPA defines “harassment” as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes are by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to sound produced by the sparkers. Based on the characteristics of the signals produced by the acoustic sources planned for use, Level A harassment is neither anticipated (even absent mitigation) nor authorized. As described previously, no serious injury or mortality is anticipated or authorized for this activity. Below we describe how the take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (e.g., previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the authorized take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (e.g., frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the

source), the environment (e.g., bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (e.g., Ellison *et al.*, 2012, Southall *et al.*, 2007, Southall *et al.*, 2021). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root mean squared (RMS) SPL of 120 dB (referenced to 1 microPascal (re 1 μ Pa)) for continuous (e.g., vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (e.g., seismic airguns) or intermittent (e.g., scientific sonar) sources.

Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

COSW’s marine site characterization surveys include the use of impulsive (i.e., sparker) sources, and therefore the RMS SPL threshold of 160 dB re 1 μ Pa is applicable.

Level A harassment—NMFS’ Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance; NMFS, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive).

The references, analysis, and methodology used in the development of the thresholds are described in NMFS (2018) Technical Guidance, which may be accessed at: www.fisheries.noaa.gov/national/marine-mammal-protection/

marine-mammal-acoustic-technical-guidance.

COSW’s marine site characterization surveys include the use of impulsive (i.e., sparker) sources. However, as discussed above, NMFS has concluded that Level A harassment is not a reasonably likely outcome for marine mammals exposed to noise through use of the sources planned for use here, and the potential for Level A harassment is not evaluated further in this document. Please see COSW’s application for details of a quantitative exposure analysis exercise (i.e., calculated Level A harassment isopleths and estimated Level A harassment exposures). COSW did not request authorization of take by Level A harassment, and no take by Level A harassment is authorized by NMFS.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

NMFS has developed a user-friendly methodology for estimating the extent of the Level B harassment isopleths associated with relevant HRG survey equipment (NMFS, 2020). This methodology incorporates frequency and directionality (when relevant) to refine estimated ensonified zones. For acoustic sources that operate with different beamwidths, the maximum beamwidth was used, and the lowest frequency of the source was used when calculating the frequency-dependent absorption coefficient. COSW used 180-degree beamwidth in the calculation for the planned sparker as is appropriate for an omnidirectional source.

NMFS considers the data provided by Crocker and Fratantonio (2016) to represent the best available information on source levels associated with HRG survey equipment and, therefore, recommends that source levels provided by Crocker and Fratantonio (2016) be incorporated in the method described above to estimate isopleth distances to harassment thresholds. In cases where the source level for a specific type of HRG equipment is not provided in Crocker and Fratantonio (2016), NMFS recommends either the source levels provided by the manufacturer be used, or, in instances where source levels provided by the manufacturer are unavailable or unreliable, a proxy from Crocker and Fratantonio (2016) be used instead. Table 1 in the **Federal Register** notice for the proposed IHA (88 FR 24574, April 21, 2023) shows the HRG equipment type used during the

planned surveys and the source levels associated with those HRG equipment types.

COSW plans to use the Applied Acoustics Dura-Spark UHD 400+400 (400 tip/300–1000 J) and the Geo-Source 200–400 Marine Multi-tip Sparker System (400 tip/300–1000 J). For all source configurations (Table 1 in the **Federal Register** notice for the proposed IHA (88 FR 24574, April 21, 2023)), the maximum power expected to be discharged from the sparker source is 1,000 J. However, Crocker and Fratantonio (2016) did not measure the Dura-Spark with an energy of 1,000 J, only 500 J, 2,000 J, and 2,400 J, so the source level values for 500 J (provided in Table 10 of Crocker and Fratantonio, 2016) were used as a proxy, as this setting was anticipated to be more representative of the application of the equipment than the next level reported for 2,000 J. The Applied Acoustics Dura-Spark was also used as a proxy for the Geo-Source 200–400 Marine Multi-tip Sparker System (400 tip/300–1000 J). Using the measured source level of 203 dB RMS SPL of the proxy, results of modeling indicated that both sparkers would produce an estimated distance of 141 m to the Level B harassment isopleth.

Results of modeling using the methodology described above indicated that, of the HRG survey equipment planned for use by the applicant (Table 1 in the **Federal Register** notice for the proposed IHA (88 FR 24574, April 21, 2023)) that has the potential to result in Level B harassment of marine mammals, both systems would produce the same distance to the Level B harassment isopleth (141 m). More detail is provided on the acoustic sources and methodology in the **Federal Register** notice for the proposed IHA; please refer to the **Federal Register** notice (88 FR 24574, April 21, 2023).

Marine Mammal Occurrence

In this section, we provide information about the occurrence of marine mammals, including density or other relevant information that will inform the take calculations.

Habitat-based density models produced by the Duke University Marine Geospatial Ecology Laboratory (Roberts *et al.*, 2016; Roberts *et al.*, 2022) represent the best available information regarding marine mammal densities in the planned survey area. These density data incorporate aerial and shipboard line-transect survey data from NMFS and other organizations and incorporate data from numerous physiographic and dynamic oceanographic and biological covariates,

and controls for the influence of sea state, group size, availability bias, and perception bias on the probability of making a sighting. These density models were originally developed for all cetacean taxa in the U.S. Atlantic in 2016 and models for all taxa were updated in 2022 (Roberts *et al.*, 2016; Roberts *et al.*, 2022). More information is available online at <https://seamap.env.duke.edu/models/Duke/EC/>. Marine mammal density estimates in the survey area (animals/km²) were obtained using the most recent model results for all taxa.

For the exposure analysis, density data from Roberts *et al.* (2022) were mapped using a geographic information system (GIS). For the survey area, the monthly densities of each species as reported by Roberts *et al.* (2022) were averaged by season; thus, a density was calculated for each species for spring, summer, fall, and winter. Density seasonal averages were calculated for both the Lease Area and the ECR Area for each species to assess the greatest average seasonal densities for each species. To be conservative since the exact timing for the survey during the year is uncertain, the greatest average seasonal density calculated for each species was carried forward in the exposure analysis, with exceptions noted later in this discussion. Estimated greatest average seasonal densities (animals/km²) of marine mammal species that may be taken incidental to the planned survey can be found in Tables 6–1 and 6–2 of COSW's IHA application. Below, we discuss how densities were assumed to apply to specific species for which the Roberts *et al.* (2022) models provide results at the genus or guild level.

There are two stocks of bottlenose dolphins that may be impacted by the surveys (Western North Atlantic Northern Migratory Coastal Stock (Coastal Stock) and Western North Atlantic Offshore Stock (Offshore Stock)); however, Roberts *et al.* (2022) do not differentiate by stock. The Coastal Stock is assumed to generally occur in waters <20 m (65 ft) and the Offshore Stock in waters deeper than 20 m (65 ft) isobath. The Lease Area is in waters >20 m (65 ft) depth and only the Offshore Stock would occur and potentially be taken by survey effort in that area. Both stocks could occur in the ECR Area, so COSW calculated separate mean seasonal densities for the portion that is <20 m depth and for the portion that is >20 m depth to use for estimating take of the Coastal and Offshore Stocks of bottlenose dolphins, respectively.

Furthermore, the Roberts *et al.* (2022) density model does not differentiate

between the different pinniped species. For seals, given their size and behavior when in the water, seasonality, and feeding preferences, there is limited information available on species-specific distribution. Density estimates from Roberts *et al.* (2022) include all seal species that may occur in the Western North Atlantic combined (*i.e.*, gray, harbor, harp, hooded). For this IHA, only gray seals and harbor seals are reasonably expected to occur in the survey area; densities of seals were split evenly between these two species.

Finally, the Roberts *et al.* (2022) density model does not differentiate between pilot whale species. While the exact latitudinal ranges of the two species are uncertain, only long-finned pilot whales are expected to occur in this project area due to their more northerly distribution and tolerance of shallower, colder shelf waters (Hayes *et al.*, 2022). We assume that all pilot whales near the project area would be long-finned pilot whales due to their range overlapping and short-finned pilot whales are not anticipated to occur as far north as the survey area (Garrison and Rosel, 2017). For this IHA, densities of pilot whales are assumed to be only long-finned pilot whale.

Take Estimation

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and authorized.

In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in harassment, radial distances to predicted isopleths corresponding to Level B harassment thresholds were calculated, as described above. The distance (*i.e.*, 141 m distance associated with both sparker systems) to the Level B harassment criterion and the total length of the survey trackline were then used to calculate the total ensonified area, or harassment zone, around the survey vessel.

COSW proposes to conduct HRG surveys for a maximum total of 30,467 km trackline length, of which a maximum of 28,290 km are in the Lease Area and 2,177 km are in the ECR Area. Of the ECR Area trackline, 400 km are in waters <20 m depth. COSW is requesting take based on the 3D scenario as it results in the largest estimated harassment zone based on the planned equipment configuration, trackline distance, and resulting ensonified area. The 3D scenario would use a three sparker array with 400 tips (either Geo-Source 200–400 or Applied Acoustics Dura-Spark UHD) activating

sequentially 750 milliseconds apart, so the Harassment Zone was modeled for each sparker and allowed for up to the maximum proposed 16.7 m spacing between each sparker (see Figure 6–2 in the application). Based on this, the distance to Level B harassment threshold from the center line of the 3D scenario survey was estimated to be 157.7 m (R). Based on the maximum estimated distance to the Level B harassment threshold and maximum total survey length, the total ensonified area is 9,611 km² (8,923 km² Lease Area and 688 km² ECR Area), based on the following formula, where the total estimated trackline length (L) in each area was used and buffered with the

horizontal distance to the Level B harassment threshold (R) for the 3D scenario to determine the total area ensonified to 160 dB RMS SPL.

$$\text{Harassment Zone} = (L \times 2R) + \pi R^2$$

This is a conservative estimate as it assumes the scenario that results in the greatest distance to the Level B harassment threshold (3D scenario) would be operated at all times during the entire survey, which may not ultimately occur.

The number of marine mammals expected to be incidentally taken during the total survey is then calculated by estimating the number of each species predicted to occur within the ensonified area (animals/km²), incorporating the

greatest seasonal estimated marine mammal densities as described above. The product is then rounded to generate an estimate of the total number of instances of harassment expected for each species over the duration of the survey (up to 293 days). A summary of this method is illustrated in the following formula, where the Harassment Zone is multiplied by the highest seasonal mean density (D) of each species or stock (animals/km²; except for pilot whales where annual density was used based on data availability).

$$\text{Estimated Take} = \text{Harassment Zone} \times D$$

The resulting take of marine mammals (Level B harassment) shown in Table 3.

TABLE 3—ESTIMATED TAKE NUMBERS AND TOTAL TAKE AUTHORIZED

Species	Estimated take —lease area	Estimated take —ECR area	Total take authorized	Percent of abundance ¹
North Atlantic right whale	23	1	24	6.8
Humpback whale	44	2	46	0.4
Fin whale	73	3	76	1.1
Sei whale	23	1	24	0.4
Minke whale	286	18	304	1.4
Sperm whale	10	0	10	0.1
Risso's dolphin	57	2	59	0.2
Long-finned pilot whale	77	1	78	0.2
Atlantic white-sided dolphin	409	18	427	0.5
Common dolphin	5,431	141	5,572	3.2
Atlantic spotted dolphin	315	5	320	0.8
Harbor porpoise	1,807	105	1,912	2
Common bottlenose dolphin (Offshore Stock)	1,212	104	1,316	2.1
Common bottlenose dolphin (Northern Migratory Coastal Stock)	0	115	115	1.7
Gray seal	1,764	191	1,955	² 0.4
Harbor seal	1,764	191	1,955	2.1

Note: take requests are all greater than average group size (see Appendix C of application).

¹ Based on the 2022 draft marine mammal SARs.

² This abundance estimate is based on the total stock abundance (including animals in Canada). The NMFS stock abundance estimate for U.S. population is only 27,300.

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and,

(2) The practicability of the measures for applicant implementation, which

may consider such things as cost and impact on operations.

The following mitigation measures must be implemented during COSW's planned marine site characterization surveys. Pursuant to section 7 of the ESA, COSW would also be required to adhere to relevant Project Design Criteria (PDC) of the NMFS' GARFO programmatic consultation (specifically PDCs 4, 5, and 7) regarding geophysical surveys along the U.S. Atlantic coast (<https://www.fisheries.noaa.gov/new-england-mid-atlantic/consultations/section-7-take-reporting-programmatics-greater-atlantic-offshore-wind-site-assessment-and-site-characterization-activities-programmatic-consultation>).

Visual Monitoring and Shutdown Zones

COSW must employ independent, dedicated, trained PSOs, meaning that the PSOs must (1) be employed by a third-party observer provider, (2) have

no tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements (including brief alerts regarding maritime hazards), and (3) have successfully completed an approved PSO training course appropriate for geophysical surveys. Visual monitoring must be performed by qualified, NMFS-approved PSOs. PSO resumes must be provided to NMFS for review and approval prior to the start of survey activities.

During survey operations (*e.g.*, any day in which use of the sparker source is planned to occur, and whenever the sparker source is in the water, whether activated or not), a minimum of one visual PSO must be on duty on each source vessel and conducting visual observations at all times during daylight hours (*i.e.*, from 30 minutes (min) prior to sunrise through 30 min following sunset). A minimum of two PSOs must be on duty on each source vessel during nighttime hours. Visual monitoring must begin no less than 30 min prior to ramp-up (described below) and must continue until 1 hr after use of the sparker source ceases.

Visual PSOs shall coordinate to ensure 360° visual coverage around the vessel from the most appropriate observation posts and shall conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner. PSOs shall establish and monitor applicable shutdown zones (see below). These zones shall be based upon the radial distance from the sparker source (rather than being based around the vessel itself).

Two shutdown zones are defined, depending on the species and context. Here, an extended shutdown zone encompassing the area at and below the sea surface out to a radius of 500 m from the sparker source (0–500 m) is defined for NARW. For all other marine mammals, the shutdown zone encompasses a standard distance of 100 m (0–100 m) during the use of the sparker. Any observations of marine mammals by crew members aboard any vessel associated with the survey shall be relayed to the PSO team.

Visual PSOs may be on watch for a maximum of 4 consecutive hours followed by a break of at least 1 hr between watches and may conduct a maximum of 12 hr of observation per 24-hr period.

Pre-Start Clearance and Ramp-Up Procedures

A ramp-up procedure, involving a gradual increase in source level output, is required at all times as part of the activation of the sparker sources when technically feasible. Operators should ramp up sparker to half power for 5 min and then proceed to full power. A 30 min pre-start clearance observation period of the shutdown zones must occur prior to the start of ramp-up. The intent of the pre-start clearance observation period (30 min) is to ensure no marine mammals are within the shutdown zones prior to the beginning of ramp-up. The intent of the ramp-up is to warn marine mammals of pending operations and to allow sufficient time for those animals to leave the immediate vicinity. All operators must adhere to the following pre-start clearance and ramp-up requirements:

- The operator must notify a designated PSO of the planned start of ramp-up as agreed upon with the lead PSO; the notification time should not be less than 60 min prior to the planned ramp-up in order to allow the PSOs time to monitor the shutdown zones for 30 min prior to the initiation of ramp-up (pre-start clearance). During this 30 min pre-start clearance period the entire shutdown zone must be visible, except as indicated below;
- Ramp-ups shall be scheduled so as to minimize the time spent with the source activated;
- A visual PSO conducting pre-start clearance observations must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed;
- Any PSO on duty has the authority to delay the start of survey operations if a marine mammal is detected within the applicable pre-start clearance zone; and
- The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that mitigation commands are conveyed swiftly while allowing PSOs to maintain watch.

The pre-start clearance requirement is waived for small delphinids and pinnipeds. Detection of a small delphinid (individual belonging to the following genera of the Family Delphinidae: *Steno*, *Delphinus*, *Lagenorhynchus*, *Stenella*, and *Tursiops*) or pinniped within the shutdown zone does not preclude beginning of ramp-up, unless the PSO confirms the individual to be of a genus other than those listed, in which case

normal pre-clearance requirements apply.

If there is uncertainty regarding identification of a marine mammal species (*i.e.*, whether the observed marine mammal(s) belongs to one of the delphinid genera for which the pre-clearance requirement is waived), PSOs may use best professional judgment in making the decision to call for a shutdown.

- Ramp-up may not be initiated if any marine mammal to which the pre-start clearance requirement applies is within the shutdown zone. If a marine mammal is observed within the shutdown zone during the 30 min pre-start clearance period, ramp-up may not begin until the animal(s) has been observed exiting the zones or until an additional time period has elapsed with no further sightings (30 min for all baleen whale species and sperm whales, 15 min for all other species).

- PSOs must monitor the shutdown zones 30 min before and during ramp-up, and ramp-up must cease and the source must be shut down upon observation of a marine mammal within the applicable shutdown zone.

- Ramp-up may occur at times of poor visibility, including nighttime, if appropriate visual monitoring has occurred with no detections of marine mammals in the 30 min prior to beginning ramp-up. Sparker activation may only occur at night where operational planning cannot reasonably avoid such circumstances.

If the acoustic source is shut down for brief periods (*i.e.*, <30 min) for reasons other than implementation of prescribed mitigation (*e.g.*, mechanical difficulty), it may be activated again without ramp-up if PSOs have maintained constant visual observation and no detections of marine mammals have occurred within the applicable shutdown zone. For any longer shutdown, pre-start clearance observation and ramp-up are required.

Shutdown Procedures

All operators must adhere to the following shutdown requirements:

- Any PSO on duty has the authority to call for shutdown of the sparker source if a marine mammal is detected within the applicable shutdown zone;
- The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch;
- When the sparker source is active and a marine mammal appears within or enters the applicable shutdown zone, the source must be shut down. When

shutdown is instructed by a PSO, the sparker source must be immediately deactivated and any dispute resolved only following deactivation; and

- Two shutdown zones are defined, depending on the species and context. An extended shutdown zone encompassing the area at and below the sea surface out to a radius of 500 m from the sparker source (0–500 m) is defined for NARW. For all other marine mammals, the shutdown zone encompasses a standard distance of 100 m (0–100 m) during the use of the sparker.

The shutdown requirement is waived for small delphinids and pinnipeds. If a small delphinid (individual belonging to the following genera of the Family Delphinidae: *Steno*, *Delphinus*, *Lagenorhynchus*, *Stenella*, and *Tursiops*) or pinniped is visually detected within the shutdown zone, no shutdown is required unless the PSO confirms the individual to be of a genus other than those listed, in which case a shutdown is required.

If there is uncertainty regarding identification of a marine mammal species (*i.e.*, whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived or one of the species with a larger shutdown zone), PSOs may use best professional judgment in making the decision to call for a shutdown.

Upon implementation of shutdown, the source may be reactivated after the marine mammal has been observed exiting the applicable shutdown zone or following a clearance period (30 min for all baleen whale species and sperm whales, 15 min for all other species) with no further detection of the marine mammal.

If a species for which authorization has not been granted, or a species for which authorization has been granted but the authorized number of takes have been met, approaches or is observed within the Level B harassment zone (158 m), shutdown must occur.

Vessel Strike Avoidance

Crew and supply vessel personnel must use an appropriate reference guide that includes identifying information on all marine mammals that may be encountered. Vessel operators must

comply with the below measures except under extraordinary circumstances when the safety of the vessel or crew is in doubt or the safety of life at sea is in question. These requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply.

Vessel operators and crews must maintain a vigilant watch for all marine mammals and slow down, stop their vessel(s), or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammals. A single marine mammal at the surface may indicate the presence of submerged animals in the vicinity of the vessel; therefore, precautionary measures should always be exercised. A visual observer aboard the vessel must monitor a vessel strike avoidance zone around the vessel (species-specific distances are detailed below). Visual observers monitoring the vessel strike avoidance zone may be third-party observers (*i.e.*, PSOs) or crew members, but crew members responsible for these duties must be provided sufficient training to (1) distinguish marine mammal from other phenomena and (2) broadly to identify a marine mammal as a NARW, other whale (defined in this context as sperm whales or baleen whales other than NARWs), or other marine mammals.

All survey vessels, regardless of size, must observe a 10-kn (18.52-km/h) speed restriction in specific areas designated by NMFS for the protection of NARWs from vessel strikes. These include all SMAs established under 50 CFR 224.105 (when in effect), any DMAs (when in effect), and Slow Zones. See www.fisheries.noaa.gov/national/conservation/endangered-species-conservation/reducing-ship-strikes-north-atlantic-right-whales for specific detail regarding these areas.

- All vessels must reduce speed to 10 kn (18.52 km/h) or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel.

- All vessels must maintain a minimum separation distance of 500 m from NARWs, baleen whales (except humpback and minke), sperm whales,

and any unidentified large whales. If a NARW, baleen whale (except humpback and minke), sperm whale, and any unidentified large whale is sighted within the relevant separation distance, the vessel must steer a course away at 10 kn (18.52 km/h) or less until the 500-m separation distance has been established. If a whale is observed but cannot be confirmed as a species other than a NARW, the vessel operator must assume that it is a NARW and take appropriate action.

- All vessels must maintain a minimum separation distance of 100 m from all humpback and minke whales.

- All vessels must, to the maximum extent practicable, attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an understanding that at times this may not be possible (*e.g.*, for animals that approach the vessel).

- When marine mammals are sighted while a vessel is underway, the vessel must take action as necessary to avoid violating the relevant separation distance (*e.g.*, attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area, reduce speed and shift the engine to neutral). This does not apply to any vessel towing gear or any vessel that is navigationally constrained.

Members of the PSO team will consult NMFS NARW reporting system and Whale Alert, daily and as able, for the presence of NARWs throughout survey operations, and for the establishment of DMAs and/or Slow Zones. It is COSW's responsibility to maintain awareness of the establishment and location of any such areas and to abide by these requirements accordingly.

Seasonal Operating Requirements

As described above, a section of the survey area partially overlaps with a portion of a NARW SMA off the port of New York/New Jersey. This SMA is active from November 1 through April 30 of each year. The survey vessel, regardless of length, would be required to adhere to vessel speed restrictions (<10 kn (18.52 km/h)) when operating within the SMA during times when the SMA is active (Table 4).

TABLE 4—NORTH ATLANTIC RIGHT WHALE DYNAMIC MANAGEMENT AREA (DMA) AND SEASONAL MANAGEMENT AREA (SMA) RESTRICTIONS WITHIN THE SURVEY AREA

Survey area	Species	DMA restrictions	Slow zones	SMA restrictions
Lease Area	North Atlantic right whale.	If established by NMFS, all of COSW's vessel will abide by the described restrictions.	If established by NMFS, all of COSW's vessel will abide by the described restrictions.	N/A.

TABLE 4—NORTH ATLANTIC RIGHT WHALE DYNAMIC MANAGEMENT AREA (DMA) AND SEASONAL MANAGEMENT AREA (SMA) RESTRICTIONS WITHIN THE SURVEY AREA—Continued

Survey area	Species	DMA restrictions	Slow zones	SMA restrictions
ECR Area (within SMA).	North Atlantic right whale.	If established by NMFS, all of COSW's vessel will abide by the described restrictions.	If established by NMFS, all of COSW's vessel will abide by the described restrictions.	November 1 through April 31 (Ports of New York/New Jersey).
ECR Area (outside SMA).	North Atlantic right whale.	If established by NMFS, all of COSW's vessel will abide by the described restrictions.	If established by NMFS, all of COSW's vessel will abide by the described restrictions.	N/A.

More information on vessel strike reduction for the NARW can be found at NMFS' website: <https://www.fisheries.noaa.gov/national/enderangered-species-conservation/reducing-vessel-strikes-north-atlantic-right-whales>.

Based on our evaluation of the applicant's planned measures, as well as other measures considered by NMFS, NMFS has determined that the planned mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.*, presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas);

- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;

- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;

- Effects on marine mammal habitat (*e.g.*, marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and

- Mitigation and monitoring effectiveness.

Monitoring Measures

Visual monitoring must be performed by qualified, NMFS-approved PSOs. COSW must submit PSO resumes for NMFS review and approval prior to commencement of the survey. Resumes should include dates of training and any prior NMFS approval, as well as dates and description of last experience, and must be accompanied by information documenting successful completion of an acceptable training course.

For prospective PSOs not previously approved, or for PSOs whose approval is not current, NMFS must review and approve PSO qualifications. Resumes should include information related to relevant education, experience, and training, including dates, duration, location, and description of prior PSO experience. Resumes must be accompanied by relevant documentation of successful completion of necessary training.

NMFS may approve PSOs as conditional or unconditional. A conditionally-approved PSO may be one who is trained but has not yet attained the requisite experience. An unconditionally-approved PSO is one who has attained the necessary experience. For unconditional approval, the PSO must have a minimum of 90 days at sea performing the role during a geophysical survey, with the

conclusion of the most recent relevant experience not more than 18 months previous.

At least one of the visual PSOs aboard the vessel must be unconditionally-approved. One unconditionally-approved visual PSO shall be designated as the lead for the entire PSO team. This lead should typically be the PSO with the most experience, who would coordinate duty schedules and roles for the PSO team and serve as primary point of contact for the vessel operator. To the maximum extent practicable, the duty schedule shall be planned such that unconditionally-approved PSOs are on duty with conditionally-approved PSOs.

A "trained lookout" may be used on a space-limited nearshore vessel (generally operating in water less than 20 m depth for no more than 12 hr/day) during required breaks for the approved PSO on duty. Project-specific training must be conducted for all vessel crew with "lookout" responsibilities prior to the start of a survey and during any changes in crew such that all relevant survey personnel are fully aware and understand the mitigation, monitoring, and reporting requirements. All vessel crew members operating as a trained lookout must be briefed in the identification of protected species that may occur in the survey area and in relevant mitigation requirements. Reference materials must be available aboard all project vessels for identification of protected species. Should a mitigation action be taken, the Trained Lookout will immediately notify the off-watch PSO to ensure that the appropriate response was taken and sightings and mitigation measures are properly documented (*i.e.*, if shutdown was called for or avoidance measures for large whales/vessel strike avoidance taken, the Trained Lookout immediately notifies the off-watch PSO). If the survey is operating within a DMA or Slow Zone, the survey may only operate with a PSO on-watch.

At least one PSO aboard each acoustic source vessel must have a minimum of 90 days at-sea experience working in the role, with no more than 18 months elapsed since the conclusion of the at-sea experience. One PSO with such experience must be designated as the lead for the entire PSO team and serve as the primary point of contact for the vessel operator. (Note that the responsibility of coordinating duty schedules and roles may instead be assigned to a shore-based, third-party monitoring coordinator.) To the maximum extent practicable, the lead PSO must devise the duty schedule such that experienced PSOs are on duty with those PSOs with appropriate training but who have not yet gained relevant experience.

PSOs must successfully complete relevant training, including completion of all required coursework and passing (80 percent or more) a written and/or oral examination developed for the training program.

PSOs must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics. The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver shall be submitted to NMFS and must include written justification. Alternate experience that may be considered includes, but is not limited to (1) secondary education and/or experience comparable to PSO duties; (2) previous work experience conducting academic, commercial, or government-sponsored marine mammal surveys; and (3) previous work experience as a PSO (PSO must be in good standing and demonstrate good performance of PSO duties).

COSW must work with the selected third-party PSO provider to ensure PSOs have all equipment (including backup equipment) needed to adequately perform necessary tasks, including accurate determination of distance and bearing to observed marine mammals, and to ensure that PSOs are capable of calibrating equipment as necessary for accurate distance estimates and species identification. Such equipment, at a minimum, shall include:

- At least one thermal (infrared) image device suited for the marine environment;
- Reticle binoculars (e.g., 7 x 50) of appropriate quality (at least one per PSO, plus backups);

- Global Positioning Units (GPSs) (at least one plus backups);
- Digital cameras with a telephoto lens that is at least 300-mm or equivalent on a full-frame single lens reflex, also known as an SLR (at least one plus backups). The camera or lens should also have an image stabilization system;
- Equipment necessary for accurate measurement of distances to marine mammal;
- Compasses (at least one plus backups);
- Means of communication among vessel crew and PSOs; and
- Any other tools deemed necessary to adequately and effectively perform PSO tasks.

The equipment specified above may be provided by an individual PSO, the third-party PSO provider, or the operator, but COSW is responsible for ensuring PSOs have the proper equipment required to perform the duties specified in the IHA.

The PSOs will be responsible for monitoring the waters surrounding the survey vessel to the farthest extent permitted by sighting conditions, including Shutdown Zones, during all HRG survey operations. PSOs will visually monitor and identify marine mammals, including those approaching or entering the established Shutdown Zones during survey activities. It will be the responsibility of the PSO(s) on duty to communicate the presence of marine mammals as well as to communicate the action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate.

PSOs must be equipped with binoculars and have the ability to estimate distance and bearing to detect marine mammals, particularly in proximity to Shutdown Zones. Reticulated binoculars must also be available to PSOs for use as appropriate based on conditions and visibility to support the sighting and monitoring of marine mammals. During nighttime operations, appropriate night-vision devices (e.g., night-vision goggles with thermal clip-ons and infrared technology) would be used. Position data would be recorded using hand-held or vessel GPS units for each sighting.

During good conditions (e.g., daylight hours; Beaufort sea state (BSS) 3 or less), to the maximum extent practicable, PSOs must also conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the active acoustic sources and between acquisition periods, to the maximum extent practicable. Any observations of marine mammals by

crew members aboard the vessel associated with the survey would be relayed to the PSO team. Data on all PSO observations would be recorded based on standard PSO collection requirements (see *Reporting Measures*). This would include dates, times, and locations of survey operations; dates and times of observations, location and weather; details of marine mammal sightings (e.g., species, numbers, behavior); and details of any observed marine mammal behavior that occurs (e.g., noted behavioral disturbances). Members of the PSO team shall consult the NMFS NARW reporting system and Whale Alert, daily and as able, for the presence of NARWs throughout survey operations.

Reporting Measures

COSW shall submit a draft comprehensive report to NMFS on all activities and monitoring results within 90 days of the completion of the survey or expiration of the IHA, whichever comes sooner. The report must describe all activities conducted and sightings of marine mammals, must provide full documentation of methods, results, and interpretation pertaining to all monitoring, and must summarize the dates and locations of survey operations and all marine mammals sightings (dates, times, locations, activities, associated survey activities). The draft report shall also include geo-referenced, time-stamped vessel tracklines for all time periods during which acoustic sources were operating. Tracklines should include points recording any change in acoustic source status (e.g., when the sources began operating, when they were turned off, or when they changed operational status such as from full array to single gun or vice versa). GIS files shall be provided in Environmental Systems Research Institute, Inc. (ESRI) shapefile format and include the Coordinated Universal Time (UTC) date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates shall be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data shall be made available. The report must summarize the information. A final report must be submitted within 30 days following resolution of any comments on the draft report. All draft and final marine mammal monitoring reports must be submitted to PR.ITP.MonitoringReports@noaa.gov, nmfs.gar.incidental-take@noaa.gov and ITP.clevenstine@noaa.gov.

PSOs must use standardized electronic data forms to record data. PSOs shall record detailed information

about any implementation of mitigation requirements, including the distance of marine mammal to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up of the acoustic source. If required mitigation was not implemented, PSOs should record a description of the circumstances. At a minimum, the following information must be recorded:

1. Vessel names (source vessel), vessel size and type, maximum speed capability of vessel;
2. Dates of departures and returns to port with port name;
3. PSO names and affiliations;
4. Date and participants of PSO briefings;
5. Visual monitoring equipment used;
6. PSO location on vessel and height of observation location above water surface;
7. Dates and times (Greenwich Mean Time (GMT)) of survey on/off effort and times corresponding with PSO on/off effort;
8. Vessel location (decimal degrees) when survey effort begins and ends and vessel location at beginning and end of visual PSO duty shifts;
9. Vessel location at 30-second intervals if obtainable from data collection software, otherwise at practical regular interval;
10. Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any change;
11. Water depth (if obtainable from data collection software);
12. Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions change significantly), including BSS and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon;
13. Factors that may contribute to impaired observations during each PSO shift change or as needed as environmental conditions change (e.g., vessel traffic, equipment malfunctions);
14. Survey activity information (and changes thereof), such as acoustic source power output while in operation, number and volume of airguns operating in an array, tow depth of an acoustic source, and any other notes of significance (i.e., pre-start clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.); and

15. Upon visual observation of any marine mammal, the following information must be recorded:

- a. Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
- b. Vessel/survey activity at time of sighting (e.g., deploying, recovering, testing, shooting, data acquisition, other);
- c. PSO who sighted the animal;
- d. Time of sighting;
- e. Initial detection method;
- f. Sightings cue;
- g. Vessel location at time of sighting (decimal degrees);
- h. Direction of vessel's travel (compass direction);
- i. Speed of the vessel(s) from which the observation was made;
- j. Identification of the animal (e.g., genus/species, lowest possible taxonomic level or unidentified); also note the composition of the group if there is a mix of species;
- k. Species reliability (an indicator of confidence in identification);
- l. Estimated distance to the animal and method of estimating distance;
- m. Estimated number of animals (high/low/best);
- n. Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);
- o. Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars, or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
- p. Detailed behavior observations (e.g., number of blows/breaths, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior before and after point of closest approach);
- q. Mitigation actions; description of any actions implemented in response to the sighting (e.g., delays, shutdowns, ramp-up, speed or course alteration, etc.) and time and location of the action;
- r. Equipment operating during sighting;
- s. Animal's closest point of approach and/or closest distance from the center point of the acoustic source; and,
- t. Description of any actions implemented in response to the sighting (e.g., delays, shutdown, ramp-up) and time and location of the action.

If a NARW is observed at any time by PSOs or personnel on the project vessel, during surveys or during vessel transit, COSW must report the sighting information to the NMFS NARW Sighting Advisory System (866-755-6622) within 2 hr of occurrence, when practicable, or no later than 24 hr after

occurrence. NARW sightings in any location may also be reported to the U.S. Coast Guard via channel 16 and through the Whale Alert app (<http://www.whalealert.org>).

In the event that personnel involved in the survey activities discover an injured or dead marine mammal, the incident must be reported to NMFS as soon as feasible by phone (866-755-6622) and by email (nmfs.gar.incidental-take@noaa.gov and PR.ITP.MonitoringReports@noaa.gov). The report must include the following information:

1. Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
2. Species identification (if known) or description of the animal(s) involved;
3. Condition of the animal(s) (including carcass condition if the animal is dead);
4. Observed behaviors of the animal(s), if alive;
5. If available, photographs or video footage of the animal(s); and
6. General circumstances under which the animal was discovered.

In the event of a vessel strike of a marine mammal by any vessel involved in the activities, COSW must report the incident to NMFS by phone (866-755-6622) and by email (nmfs.gar.incidental-take@noaa.gov and PR.ITP.MonitoringReports@noaa.gov) as soon as feasible. The report would include the following information:

1. Time, date, and location (latitude/longitude) of the incident;
2. Species identification (if known) or description of the animal(s) involved;
3. Vessel's speed during and leading up to the incident;
4. Vessel's course/heading and what operations were being conducted (if applicable);
5. Status of all sound sources in use;
6. Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;
7. Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
8. Estimated size and length of animal that was struck;
9. Description of the behavior of the marine mammal immediately preceding and/or following the strike;
10. If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;
11. Estimated fate of the animal (e.g., dead, injured but alive, injured and

moving, blood or tissue observed in the water, status unknown, disappeared); and

12. To the extent practicable, photographs or video footage of the animal(s).

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “taken” through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS’ implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all the species listed in Table 1, given that some of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are included as separate subsections below. Specifically, we provide additional discussion related to NARW and to other species currently experiencing UMEs.

NMFS does not anticipate that serious injury or mortality would occur as a result from HRG surveys, even in the absence of mitigation, and no serious injury or mortality is authorized. As discussed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section, non-auditory physical effects, auditory physical effects, and vessel strike are not expected to occur. NMFS expects that all potential takes would be in the form of Level B harassment in the form of temporary avoidance of the area or decreased foraging (if such activity was occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.*, Southall *et al.*, 2007, Ellison *et al.*, 2012).

In addition to being temporary, the maximum expected harassment zone around a survey vessel is 158 m (rounded up from the 157.7 m Level B harassment isopleth). Therefore, the ensonified area surrounding each vessel is relatively small compared to the overall distribution of the animals in the area and their use of the habitat. Feeding behavior is not likely to be significantly impacted as prey species are mobile and are broadly distributed throughout the survey area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the temporary nature of the disturbance and the availability of similar habitat and resources in the surrounding area, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

There are no rookeries, mating or calving grounds known to be biologically important to marine mammals within the planned survey area and there are no feeding areas known to be biologically important to marine mammals within the survey area. There is no designated critical habitat for any ESA-listed marine mammals in the survey area.

North Atlantic Right Whales

The status of the NARW population is of heightened concern and, therefore, merits additional analysis. As noted previously, elevated NARW mortalities began in June 2017 and there is an active UME. Overall, preliminary findings attribute human interactions, specifically vessel strikes and entanglements, as the cause of death for the majority of NARWs. As noted previously, the survey area overlaps a

migratory corridor BIA for NARWs that extends from Massachusetts to Florida and from the coast to beyond the shelf break. Due to the fact that the planned survey activities are temporary (will occur for up to 1 year) and the spatial extent of sound produced by the survey would be small relative to the spatial extent of the available migratory habitat in the BIA, NARW migration is not expected to be impacted by the survey. This important migratory area is approximately 269,488 km² in size (compared with the worst case scenario of approximately 9,611 km² of total estimated Level B harassment ensonified area associated with the Survey Area) and is comprised of the waters of the continental shelf offshore the East Coast of the United States, extending from Florida through Massachusetts.

Given the relatively small size of the ensonified area, it is unlikely that prey availability would be adversely affected by HRG survey operations. Required vessel strike avoidance measures will also decrease risk of vessel strike during migration; no vessel strike is expected to occur during COSW’s planned activities. Additionally, only very limited take by Level B harassment of NARWs has been requested and is authorized by NMFS as HRG survey operations are required to maintain and implement a 500-m shutdown zone. The 500-m shutdown zone for NARWs is conservative, considering the Level B harassment zone for the most impactful acoustic source (*i.e.*, sparker) is estimated to be 158 m, and thereby minimizes the intensity and duration of any potential incidents of behavioral harassment for this species. As noted previously, Level A harassment is not expected due to the small estimated zones in conjunction with the aforementioned shutdown requirements. NMFS does not anticipate NARW takes that would result from COSW’s planned activities will impact annual rates of recruitment or survival. Thus, any takes that occur will not result in population level impacts.

Other Marine Mammal Species With Active UMEs

As noted previously, there are several active UMEs occurring in the vicinity of COSW’s Survey Area. Elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida since January 2016. Of the cases examined, approximately half had evidence of human interaction (*i.e.*, vessel strike, entanglement). The UME does not yet provide cause for concern regarding population-level impacts. Despite the

UME, the relevant population of humpback whales (the West Indies breeding population, or distinct population segment) remains stable at approximately 12,000 individuals.

Beginning in January 2017, elevated minke whale strandings have occurred along the Atlantic coast from Maine through South Carolina, with highest numbers in Massachusetts, Maine, and New York. This event does not provide cause for concern regarding population level impacts, as the likely population abundance is greater than 20,000 whales.

Elevated numbers of harbor seal and gray seal mortalities were first observed between 2018–2020 and, as part of a separate UME, again in 2022. These have occurred across Maine, New Hampshire, and Massachusetts. Based on tests conducted so far, the main pathogen found in the seals is phocine distemper virus (2018–2020) and avian influenza (2022), although additional testing to identify other factors that may be involved in the UMEs is underway. The UMEs do not provide cause for concern regarding population-level impacts to any of these stocks. For harbor seals, the population abundance is over 60,000 and annual M/SI (339) is well below PBR (1,729) (Hayes *et al.*, 2022). The population abundance for gray seals in the United States is over 27,000, with an estimated abundance, including seals in Canada, of approximately 450,000. In addition, the abundance of gray seals is likely increasing in the U.S. Atlantic as well as in Canada (Hayes *et al.*, 2021, Hayes *et al.*, 2022).

The required mitigation measures are expected to reduce the number and/or severity of takes for all species listed in Table 1, including those with active UMEs, to the level of least practicable adverse impact. In particular, they would provide animals the opportunity to move away from the sound source before HRG survey equipment reaches full energy, thus preventing them from being exposed to sound levels that have the potential to cause injury. No Level A harassment is anticipated, even in the absence of mitigation measures, or authorized.

NMFS expects that takes would be in the form of short-term Level B harassment by way of brief startling reactions and/or temporary vacating of the area, or decreased foraging (if such activity was occurring)—reactions that (at the scale and intensity anticipated here) are considered to be of low severity, with no lasting biological consequences. Since both the sources and marine mammals are mobile, animals would only be exposed briefly

to a small ensonified area that might result in take. Additionally, required mitigation measures would further reduce exposure to sound that could result in more severe behavioral harassment.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- No Level A harassment (PTS) is anticipated, even in the absence of mitigation measures, or authorized;
- Foraging success is not likely to be significantly impacted as effects on species that serve as prey species for marine mammals from the survey are expected to be minimal;
- The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the ensonified areas during the planned survey to avoid exposure to sounds from the activity;
- Take is anticipated to be by Level B harassment only consisting of brief startling reactions and/or temporary avoidance of the ensonified area;
- Survey activities will occur in such a comparatively small portion of the BIA for the NARW migration that any avoidance of the area due to survey activities would not affect migration. In addition, mitigation measures require shutdown at 500 m (over three times the size of the Level B harassment zone of 158 m) to minimize the effects of any Level B harassment take of the species; and,
- The planned mitigation measures, including visual monitoring and shutdowns, are expected to minimize potential impacts to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the planned monitoring and mitigation measures, NMFS finds that the total marine mammal take from the planned activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are

available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

NMFS authorizes incidental take by Level B harassment only of 15 marine mammal species with 16 managed stocks. The total amount of takes authorized relative to the best available population abundance is less than 7 percent for any of the 16 managed stocks (Table 3). The take numbers authorized are considered conservative estimates for purposes of the small numbers determination as they assume all takes represent different individual animals, which is unlikely to be the case.

Based on the analysis contained herein of the planned activity (including the planned mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the ESA (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

NMFS Office of Protected Resources (OPR) has authorized take of four species of marine mammals which are listed under the ESA, including NARW,

fin whale, sei whale, and sperm whale, and determined these activities fall within the scope of activities analyzed in the NMFS GARFO programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the three Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021).

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our proposed action (*i.e.*, the issuance of an IHA) and alternatives with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of this IHA qualifies to be categorically excluded from further NEPA review.

Authorization

NMFS has issued an IHA to COSW for the potential harassment of small numbers of 15 marine mammal species (16 stocks) incidental to conducting marine site characterization surveys in coastal waters off of New Jersey and New York in the New York Bight for a period of 1 year that includes the previously explained mitigation, monitoring, and reporting requirements. The IHA can be found at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-community-offshore-wind-llc-marine-site-characterization>.

Dated: June 27, 2023.

Kimberly Damon-Randall,

Director, Office of Protected Resources,
National Marine Fisheries Service.

[FR Doc. 2023-13990 Filed 6-29-23; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) and service(s) from the Procurement List previously furnished by such agencies.

DATES: Date added to and deleted from the Procurement List: July 30, 2023.

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: Michael R. Jurkowski, Telephone: (703) 785-6404, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Additions

On 3/31/2023, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to 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 material presented to it concerning capability of qualified nonprofit agencies to provide the service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the service(s) listed below are 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 any additional reporting, recordkeeping, or other compliance requirements for small entities other than the small organizations that will furnish the service(s) to the Government.
2. The action will result in authorizing small entities to furnish the 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 service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service(s) are added to the Procurement List:

Service(s)

Service Type: Custodial Service
Mandatory for: U.S. Army, Oahu, HI
Designated Source of Supply: Work Now Hawaii, Honolulu, HI
Contracting Activity: DEPT OF THE ARMY, 0413 AQ HQ

Deletions

On 3/3/2023, 3/10/2023, 3/17/2023, 4/7/2023, 4/21/2023, and 5/5/2023, 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): 7530-01-590-7110—Paper, Thermal, Roll, White, 2 1/4" x 165'
Designated Source of Supply: CINCINNATI ASSOCIATION FOR THE BLIND AND VISUALLY IMPAIRED, Cincinnati, OH
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR (2, NEW YORK, NY

*Service(s)**Service Type:* Janitorial/Custodial*Mandatory for:* North Dakota Maintenance Office & Bismarck Warehouse, Bismarck ND*Designated Source of Supply:* Pride, Inc., Bismarck, ND*Contracting Activity:* ENERGY, DEPARTMENT OF, WESTERN-UPPER GREAT PLAINS REGION*Service Type:* Janitorial/Custodial*Mandatory for:* North Dakota Maintenance Office, 707 North Bismarck Expressway, Bismarck, ND*Designated Source of Supply:* Pride, Inc., Bismarck, ND*Contracting Activity:* ENERGY, DEPARTMENT OF, WESTERN-UPPER GREAT PLAINS REGION*Service Type:* Janitorial/Custodial*Mandatory for:* Bureau of Land Management, Farmington District Office, 6251 College Boulevard, Farmington, NM*Designated Source of Supply:* Presbyterian Medical Services, Santa Fe, NM*Contracting Activity:* BUREAU OF LAND MANAGEMENT, NM-NEW MEXICO STATE OFFICE*Service Type:* Laundry Service*Mandatory for:* Pennsylvania Air National Guard, 171st Air Refueling Wing, Aircrew Alert Facility, 300 Tanker Road, Coraopolis, PA*Designated Source of Supply:* Hancock County Sheltered Workshop, Inc., Weirton, WV*Contracting Activity:* DEPT OF THE ARMY, W7NX USPFO ACTIVITY PA ARNG*Service Type:* Janitorial Service*Mandatory for:* USDA Forest Service, White Mountain National Forest Headquarters, 71 White Mountain Dr, Campton, NH*Designated Source of Supply:* Community Workshops, Inc., Boston, MA*Contracting Activity:* FOREST SERVICE, ALLEGHENY NATIONAL FOREST*Service Type:* Custodial and Related Services*Mandatory for:* GSA PBS Region 8, Missoula Federal Building, 200 East Broadway, Missoula, MT*Designated Source of Supply:* Opportunity Resources, Inc., Missoula, MT*Contracting Activity:* PUBLIC BUILDINGS SERVICE, PBS R8*Service Type:* Document Destruction Service*Mandatory for:* Social Security ODAR, Falls Church, VA (offsite: 9104 Red Branch Road, Columbia, MD), One Skyline Tower, 5107 Leesburg Pike, Falls Church, VA*Contracting Activity:* SOCIAL SECURITY ADMINISTRATION*Service Type:* Janitorial/Custodial*Mandatory for:* US Army Reserve, PFC Anthony F. Efrati USARC, 100 Front Street, Weirton, WV*Designated Source of Supply:* Hancock County Sheltered Workshop, Inc., Weirton, WV*Contracting Activity:* DEPT OF THE ARMY, W6QK ACC-PICA*Service Type:* Dispatcher*Mandatory for:* Defense Logistics Agency,

Defense Supply Center Richmond, 8000 Jefferson Davis Highway, Richmond, VA

Designated Source of Supply: SOAR 365, Richmond, VA*Contracting Activity:* DEFENSE LOGISTICS AGENCY, DCSO RICHMOND*Service Type:* Firewatch/Tank Void/Lead Handler Support Services*Mandatory for:* Puget Sound Naval Ship Yards at Bremerton, Bangor and Keyport, WA 1400 Farragut Avenue, Bremerton, WA*Designated Source of Supply:* Skookum Educational Programs, Bremerton, WA*Contracting Activity:* DEPT OF THE NAVY, NAVSUP FLT LOG CTR PUGET SOUND*Service Type:* Custodial Service*Mandatory for:* USDA Forest Service, Bridger-Teton National Forest Supervisor's Office, Jackson Ranger District & Teton Interagency Helibase, Jackson, WY, 340 N. Cache Street and 1260 E. Airport Road Jackson, WY*Designated Source of Supply:* Development Workshop, Inc., Idaho Falls, ID*Contracting Activity:* FOREST SERVICE, USDA FOREST SERVICE*Service Type:* Janitorial/Custodial*Mandatory for:* US Department of Energy, Energy Drive Facility, Idaho National Laboratory, Bldg. IF-609, 850 Energy Drive, Idaho Falls, ID*Designated Source of Supply:* Development Workshop, Inc., Idaho Falls, ID*Contracting Activity:* ENERGY, DEPARTMENT OF, IDAHO OPERATIONS OFFICE**Michael R. Jurkowski,***Acting Director, Business Operations.*

[FR Doc. 2023-13947 Filed 6-29-23; 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 and service(s) 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) previously furnished by such agencies.**DATES:** Comments must be received on or before: July 30, 2023.**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 submitcomments contact: Michael R. Jurkowski, Telephone: (703) 785-6404, or email CMTEFedReg@AbilityOne.gov.**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.**Additions**

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

*Service(s)**Service Type:* Janitorial Service*Mandatory for:* Federal Aviation Administration, Fayetteville Air Traffic Control Tower, Fayetteville, NC*Designated Source of Supply:* OE Enterprises, Inc., Hillsborough, NC*Contracting Activity:* FEDERAL AVIATION ADMINISTRATION, 697DCK REGIONAL ACQUISITIONS SVCS*Service Type:* Grounds Maintenance*Mandatory for:* U.S. Department of Justice, Robert F. Kennedy Building, Washington, DC*Designated Source of Supply:* Melwood Horticultural Training Center, Inc., Upper Marlboro, MD*Contracting Activity:* OFFICES, BOARDS AND DIVISIONS, U.S. DEPT OF JUSTICE*Service Type:* Grounds/Range Maintenance*Mandatory for:* US Air Force, Camp Bullis US Army Training Center, San Antonio, TX*Designated Source of Supply:* Goodwill Industries of San Antonio Contract Services, San Antonio, TX*Contracting Activity:* DEPT OF THE AIR FORCE, FA3016 502 CONS CL, JBASA**Deletions**

The following product(s) are proposed for deletion from the Procurement List:

*Product(s)**NSN(s)—Product Name(s):*

7530-01-346-4296—Folder, File, Medical Records, Type II, Manila, Letter

7530-01-347-5227—Folder, File, Administrative Records, Type I, Manila, Letter

Designated Source of Supply: LC Industries, Inc., Durham, NC*Contracting Activity:* STRATEGIC ACQUISITION CENTER, FREDERICKSBURG, VA*NSN(s)—Product Name(s):*

7530-01-346-4296—Folder, File, Medical Records, Type II, Manila, Letter

7530-01-347-5227—Folder, File, Administrative Records, Type I, Manila, Letter

Designated Source of Supply: CLOVERNOOK CENTER FOR THE BLIND AND VISUALLY IMPAIRED, Cincinnati, OH
Contracting Activity: STRATEGIC ACQUISITION CENTER, FREDERICKSBURG, VA

NSN(s)—Product Name(s):

4235-01-572-3892—Sorbent, Hazardous Material, Granular, Biobased, 20 LB
 4235-01-572-3902—Sorbent, Hazardous Material, Granular, Biobased, 4 LB
 4235-01-599-3952—Sorbent, Hazardous Material, Granular, Biobased, 40 LB

Designated y Source of Supply: San Antonio Lighthouse for the Blind, San Antonio, TX

Contracting Activity: DLA AVIATION, RICHMOND, VA

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2023-13946 Filed 6-29-23; 8:45 am]

BILLING CODE 6353-01-P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 88 FR 41085, June 23, 2023.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 9:00 a.m. EDT, Friday, June 30, 2023.

CHANGES IN THE MEETING: The meeting has been canceled.

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, Secretary of the Commission, 202-418-5964.

(Authority: 5 U.S.C. 552b.)

Dated: June 28, 2023.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2023-14062 Filed 6-28-23; 4:15 pm]

BILLING CODE 6351-01-P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Privacy Act of 1974; Matching Program

AGENCY: Corporation for National and Community Service.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988, OMB Final Guidance Interpreting the Provisions of the Computer Matching and Privacy Protection Act of 1988, and OMB Circular No. A-130, "Management of Federal Information Resources," the Corporation for National and

Community Service (operating as AmeriCorps) is issuing a public notice of the computer matching program with the Social Security Administration (SSA).

DATES: Comments must be received by July 31, 2023. If AmeriCorps determines that significant changes to the matching agreement are necessary, it shall publish a revised notice with an additional 30-day public comment period.

AmeriCorps has filed a report of the subject computer matching agreement with the Office of Management and Budget (OMB) and Congress. The matching program will begin October 1, 2023 or 40 days after the date of AmeriCorps' submissions to OMB and Congress, whichever is later, and will continue for 18 months after the effective date. It may be extended for an additional 12 months thereafter, if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: You may submit comments identified by the title of the information collection activity, by any of the following methods.

(1) *By mail sent to:* AmeriCorps, Attention Terrence King, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through www.regulations.gov.

Comments submitted in response to this notice may be made available to the public through regulations.gov. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Terrence King, Senior Security Engineer, 202-815-4246, or by email at tking@cns.gov.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub.

L. 100-503), regulates the use of computer matching agreements by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. Among other things, it requires Federal agencies involved in computer matching agreements to publish a notice in the **Federal Register** regarding the establishment of the matching program.

This agreement will be in effect for a period of 18 months, with a provision for a one-time extension for a period not to exceed 12 months. To renew this agreement, both AmeriCorps and SSA must certify to their respective Data Integrity Boards that: (1) the matching program will be conducted without change; and (2) the matching program has been conducted in compliance with the original agreement.

AmeriCorps will provide SSA with a data file including each applicant's and potential education award recipient's social security number, first and last names, and date of birth. SSA will conduct a match on the identifying information. If the match does not return a result verifying the individual's citizenship status, AmeriCorps will contact the individual or the grant recipient program that selected the individual to verify the results in accordance with the requirements of 5 U.S.C. 552a(p) and applicable OMB guidelines. The affected individual will have an opportunity to contest the accuracy of the information provided by SSA. The applicant will have at least 30 days from the date of the notice to provide clear and convincing evidence of the accuracy of the social security number, proof of U.S. citizenship, or both.

Applicants will be informed at the time of application that information provided on the application is subject to verification through a computer matching program. The application package will contain a privacy certification notice that the applicant must sign, authorizing AmeriCorps to verify the information provided.

For transferees of education awards, at the time an award is transferred, AmeriCorps will provide the individual notice that the SSN is subject to verification through a computer matching program. AmeriCorps will send a privacy notice to the transferee, and in the case of a minor, to the parent or legal guardian. The transferee, parent, or legal guardian must sign the privacy certification authorizing AmeriCorps to verify the information provided.

AmeriCorps will furnish a copy of this notice to both Houses of Congress and the Office of Management and Budget.

Participating Agencies: Participants in this computer matching program are the Social Security Administration (source agency) and the Corporation for National and Community Service (recipient agency).

Authority for Conducting the Matching Program: This agreement is executed in compliance with the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (5 U.S.C. 552a), and the regulations and guidance promulgated under the Act.

SSA's legal authority to enter into this agreement is section 1106 of the Social Security Act (42 U.S.C. 1306) and the regulations promulgated pursuant to that section (20 CFR part 401). The authority for SSA's disclosure of record information is 5 U.S.C. 552a(b)(3).

Section 146(a)(3) of the National and Community Service Act of 1990 (NCSA; 42 U.S.C. 12602(a)) sets forth the eligibility requirements for an individual to receive an Education Award from the National Service Trust upon successful completion of a term of service in an approved national service position. Section 1711 of the Serve America Act (Pub. L. 111–13) directs AmeriCorps to enter into a data matching agreement to verify statements made by an individual declaring that such individual is in compliance with section 146(a)(3) of the NCSA by comparing information provided by the individual with information relevant to such a declaration in the possession of another Federal agency. In accordance with the study AmeriCorps completed pursuant to section 1711 of the Serve America Act, AmeriCorps determined that a data matching program with SSA is the most effective means to verify an individual's statement that they are in compliance with section 146(a)(3) of the NCSA.

Purpose(s): The computer match between AmeriCorps and SSA will enable AmeriCorps to verify the social security numbers of individuals applying to serve in approved national service positions and those designated to receive national service education awards under the NCSA and verify statements made by those individuals regarding their citizenship status.

Categories of Individuals: Each individual who is eligible to receive an education award or applies to serve in an approved national service position, including positions in AmeriCorps State and National, AmeriCorps VISTA, AmeriCorps NCCC, and Serve America Fellows, must, at the time of acceptance of an education award or application to serve, certify that they meet the citizenship eligibility criteria to serve in

the position that is, that they are a citizen, national, or lawful permanent resident of the United States.

Categories of Records: The Master Files of Social Security Number Holders and SSN Applications SSA/OTSO 60–0058, last published in full on December 29, 2010 (75 FR 82121), as amended on July 5, 2013 (78 FR 40542) and February 13, 2014 (79 FR 8780) maintains records about each individual who has applied for and obtained an SSN. SSA uses information from this system to assign SSNs.

System(s) of Records: The information AmeriCorps provides from the AmeriCorps Member Individual Account, Corporation-8 system of records, published in full on March 5, 1999 (64 FR 10879–10893), as amended on August 1, 2000, (65 FR 46890–46905) and July 25, 2002 (67 FR 48616–48617) will be matched against this system of records and verification results will be disclosed under the applicable routine use.

Gina Cross,

Senior Agency Official for Privacy.

[FR Doc. 2023–13943 Filed 6–29–23; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2023–OS–0045]

Privacy Act of 1974; System of Records

AGENCY: Department of Defense (DoD).

ACTION: Notice of rescindment of multiple System of Records Notices (SORNs).

SUMMARY: In accordance with the Privacy Act of 1974, the DoD is providing notice to rescind 26 Privacy Act SORNs. A description of these systems can be found in the table in the **SUPPLEMENTARY INFORMATION** section. Additionally, the DoD is issuing a direct final rule, published elsewhere in this issue of the **Federal Register**, to amend its regulation and remove the Privacy Act exemption rules for 14 SORNs (items (a) through (m), and (s) in the aforementioned table) rescinded in this notice.

DATES: The rescindment of these SORNs is effective June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, Privacy and Civil Liberties Division, Directorate for Privacy, Civil Liberties and Freedom of Information, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency,

Department of Defense, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700, OSD.DPCLTD@mail.mil, (703) 571–0070.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, and as part of its ongoing integration and management efforts, the DoD is removing 26 Privacy Act SORNs from its inventory. Upon review of its inventory, DoD determined it no longer needs or uses these system of records because the records are covered by other SORNs; therefore, DoD is retiring these SORNs (items (a) through (z) in the table) for reasons listed as follows.

Items (a) through (r) in the table are rescinded because the records are now maintained as part of the DoD-wide system of records titled DoD–0008, Freedom of Information Act and Privacy Act Records (FOIA/PA Records), published in the **Federal Register** on December 22, 2021 (86 FR 72586).

Items (s) through (w) in the table are rescinded because the records are now maintained as a part of the DoD-wide system of records titled DoD 0006, Military Justice and Civilian Criminal Case Records, published in the **Federal Register** on May 25, 2021 (86 FR 28086).

Items (x) through (z) in the table are rescinded because the records are now maintained as a part of the DoD-wide system of records titled DoD–0009, Defense Mass Transportation Benefits Records (DMTBR), published in the **Federal Register** on January 7, 2022 (87 FR 943).

DoD SORNs have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Privacy, Civil Liberties, and Freedom of Information Directorate website at <https://dpcltd.defense.gov>.

II. Privacy Act

Under the Privacy Act, a “system of records” is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, DoD has provided a report of this SORN bulk rescindment to OMB and Congress.

System name	Number	Descriptions	History
(a) Information Requests—Freedom of Information Act.	F033 AF A	Was established to process FOIA requests and to assist the Department of the Air Force in carrying out responsibilities under the FOIA.	May 19, 2011, 76 FR 28963.
(b) Privacy Act Request Files	F033 AF B	Was established to record, process and coordinate individual requests for access to, or amendment of, personal records, and appeals on denials of requests for access or amendments to personal records; and to compile information for reports, and to ensure timely response to requesters under the Privacy Act.	April 07, 2003, 68 FR 16788.
(c) Privacy Case Files	A0340–21 OAA	Was established to process and coordinate requests for access to and amendment of individuals' records; to process appeals on denials of requests for access to or amendment of individuals' records by the data subject against agency rulings; and to ensure timely response to requesters under the Privacy Act.	July 11, 2014, 79 FR 40080; December 08, 2005, 70 FR 72997.
(d) FOIA Request/Appeal Files and Tracking System.	NM05720–1	Was established to track, process, and coordinate requests/appeals/litigation made under the provisions of the FOIA; to provide responses to requests, including requests for access to information regarding FOIA requests and/or what is being requested under the provisions of the FOIA; and to compile data for FOIA reporting requirements.	June 13, 2013, 78 FR 35610; April 2, 2008, 73 FR 17961.
(e) Privacy Act Request/Amendment Files and Tracking System.	NM05211–1	Was established to track, process, and coordinate individual requests for access and amendment of personal records; to process appeals on denials of requests for access or amendment to personal records; to compile information for reports; and to ensure timely response to requesters under the Privacy Act.	June 13, 2013, 78 FR 35607; April 2, 2008, 73 FR 17959.
(f) Information Requests—Freedom of Information Act (FOIA) and Privacy Act.	LDIA 0010	Was established to meet regulatory requirements of the FOIA and Privacy Act and to provide documentation in response to requests from the public sector for information, which is originated by or contained in the files of the Defense Intelligence Agency; and to provide information for compiling reports required by public disclosure statutes and to assist the Department of Justice in preparation of the Agency's defense in any lawsuit arising under these statutes.	May 03, 2012; 77 FR 26258; July 19, 2006, 71 FR 41003.
(g) Freedom of Information Act/Privacy Act Requests and Administrative Appeal Records.	S510.30	Was established to process access requests and administrative appeals under the FOIA, access and amendment requests and administrative appeals under the Privacy Act; for the purpose of participating in litigation regarding agency action on such requests and appeals; and for the purpose of assisting the Defense Logistics Agency in carrying out any other responsibilities under the FOIA and the Privacy Act.	April 18, 2011, 76 FR 21706.
(h) Privacy and Freedom of Information Request Records.	V1–01	Was established to facilitate responses to individual requests for information under the FOIA and Privacy Act; to document actions taken in subsequent requests (including correction and amendment actions), appeals, or litigation; and to provide a basis for reports and implementing directives.	January 28, 2013, 78 FR 5788; July 14, 1999, 64 FR 37935.
(i) Freedom of Information Act and Privacy Act Case Files.	HDTRA 021	Was established to process access requests under the FOIA and access and amendment requests under the Privacy Act; to administer appeals and litigation arising from such requests; and to assist DTRA in discharging any other responsibilities under the FOIA and the Privacy Act.	September 18, 2012; 77 FR 57561; August 7, 2006, 71 FR 44668.
(j) Freedom of Information Act (FOIA) and Privacy Act (PA) Case Files.	INGB 001	Was established to maintain FOIA and Privacy Act requests and administrative appeals; for participating in litigation regarding agency action on such requests and appeals; and for assisting the National Guard Bureau in carrying out any other responsibilities under the FOIA and Privacy Act.	July 17, 2014; 79 FR 41678.
(k) Privacy Act and Freedom of Information Act Case Files.	CIG–01	Was established to process FOIA and Privacy Act requests and administrative appeals; for participating in litigation regarding agency action on such requests and appeals; for amendment to records made under the Privacy Act and to document DoD Office of Inspector General (DoD OIG) actions in response to these requests; and for assisting the DoD OIG in carrying out any other responsibilities under the FOIA.	May 31, 2006; 71 FR 30883.
(l) Freedom of Information Act (FOIA) Case Files.	DWHS E02	Was established to process FOIA requests and administrative appeals; for participating in litigation regarding agency action on such requests and appeals; and for assisting the DoD in carrying out any other responsibilities under the FOIA.	May 21, 2015, 80 FR 29312; January 28, 2013, 78 FR 5783; December 8, 2010, 75 FR 76432.
(m) Privacy Act Case Files	DWHS E04	Was established to process Privacy Act requests and administrative appeals; for participating in litigation regarding agency action on such requests and appeals; and for assisting the Department of Defense in carrying out any other responsibilities under the Privacy Act.	April 10, 2015, 80 FR 19293; October 29, 2012, 77 FR 65539; December 8, 2010, 75 FR 76423.
(n) Freedom of Information Act Requests.	T5020	Was established to control administrative processing of requests for information made under the provisions of the FOIA, and to record statistics for the annual FOIA report.	July 12, 2013, 78 FR 41916; December 15, 2008, 73 FR 76005.
(o) Privacy Act Request	T5020a	Was established to record, process, and coordinate individual requests for access to, or amendment of personal records, and appeals of denials of request for access or amendment to personal records, made under the Privacy Act.	June 24, 2013; 78 FR 37799; February 23, 2009, 74 FR 8064.
(p) Freedom of Information Act/Privacy Act Requests and Administrative Appeal Records.	EDHA 01	Was established to process access requests and administrative appeals under FOIA; to process access and amendment requests and administrative appeals under the Privacy Act; for litigation regarding agency action on such requests and administrative appeals; and to assist the Defense Health Agency in carrying out any other responsibility under FOIA or the Privacy Act.	August 22, 2014, 79 FR 49761.

System name	Number	Descriptions	History
(q) Freedom of Information Act File (FOIA).	K890.01	Was established to make available to the public the maximum amount of information concerning the operations and activities of the Defense Information Systems Agency (DISA); to receive, process, and respond to requests for information under FOIA; to review and deny requests for information under provisions of FOIA and to forward applicable correspondence to the Director, DISA when the denial may be contested or appealed; and for review in the event of judicial action.	June 11, 2012, 77 FR 34357; March 10, 2008, 73 FR 12711.
(r) Privacy Act Records	K890.20	Was established for the purposes of processing access and amendment requests and administrative appeals under the Privacy Act; participating in litigation regarding agency action on such requests and appeals; and assisting the Defense Information Systems Agency in carrying out any other responsibilities under the Privacy Act.	September 13, 2012, 77 FR 56630; February 22, 1993, 58 FR 10562.
(s) Military Justice and Magistrate Court Records.	F051 AFJA I	Was established to investigate, adjudicate and prosecute adverse action cases, Article 138 complaints, and other administrative and criminal actions related to violation of federal law and regulations and state law occurring on and off a military installation; for use by appellate authorities and federal and state licensing authorities; for statistical purposes and to manage case processing; and to provide victims and witnesses information consistent with the requirements of the Victim and Witness Assistance Program, the Victims' Rights and Restitution Act of 1990, and other laws and regulations governing the providing of information to victims and witnesses related to military justice actions and criminal cases and their administrative disposition.	July 22, 2010, 75 FR 42720.
(t) Military Justice Correspondence and Information File.	N05810-2	Was established to provide a record of individual inquiries and Department of the Navy Judge Advocate General responses concerning military justice related matters, to maintain background information on military justice matters to assist in responding to inquiries, and to provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.	January 08, 2001; 66 FR 1321.
(u) Magistrate Court Case Files ...	MJA00003	Was established to provide a record of summons, warrants, investigative reports and complaints for use by military prosecutors in the preparation of cases of trial.	August 17, 1999, 64 FR 44698, 44702.
(v) Marine Corps Command Legal Files.	MJA00009	Was established to provide a record of actions for use by commanding officers or officers in charge who have authority to convene a special court-martial. The records are used as required to initiate, refer or complete appropriate disciplinary proceedings.	May 18, 1995, 60 FR 26723; February 8, 1995, at 60 FR 7523.
(w) JA Division, HQMC Correspondence Control Files.	MJA00017	Was established to provide a record of action taken on all correspondence received by the Judge Advocate Division, Headquarters, Marine Corps on individual inquiries.	August 03, 1993, 58 FR 41254, 41257.
(x) Transportation Incentive Program System (TIPS).	T4500c	Was established to manage the mass transportation program for Defense Finance Accounting Service (DFAS) civilian and DFAS non-appropriated fund employees who applied for and were in receipt of mass transit subsidies.	October 27, 2015, 80 FR 65717.
(y) Transportation Incentive Program Records.	T4165	Was established to support the Transportation Incentive Program for receipt and processing of employee applications; distribution of fare media; to reimburse participants; to track the use of funds used to support the program; to evaluate employee participation in the program; and to prevent misuse of the funds involved for participants outside the National Capitol Region. Participant records were used by the DFAS site parking authorities for the purpose of identifying those individuals who receive a fare subsidy and also make use of a DFAS site parking sticker.	February 10, 2009, 74 FR 6583.
(z) Mass Transportation Benefit Program—Outside the National Capital Region (ONCR).	S400.30	Was established to manage the Defense Logistics Agency Mass Transportation Benefit Program for participants Outside the National Capitol Region, including receipt and processing of employee applications and distribution of the fare media to employees; to reimburse participants; to track the use of funds used to support the program; to evaluate employee participation in the program; to prevent misuse of the funds involved; and to identify individuals who receive a fare subsidy and also make use of a DLA Primary Level Field Activity parking sticker.	May 03, 2012, 77 FR 26261; September 22, 2009, 74 FR 48233.

Dated: June 27, 2023.

Aaron T. Siegel,

*Alternate OSD Federal Register Liaison
Officer, Department of Defense.*

[FR Doc. 2023-13970 Filed 6-29-23; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0044]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Revocation of Consent To Share Federal Tax Information Form**AGENCY:** Federal Student Aid (FSA), Department of Education (ED).**ACTION:** Notice.**SUMMARY:** In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).**DATES:** Interested persons are invited to submit comments on or before July 31, 2023.**ADDRESSES:** Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.**SUPPLEMENTARY INFORMATION:** The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.*Title of Collection:* Revocation of Consent to Share Federal Tax Information Form.*OMB Control Number:* 1845–NEW.*Type of Review:* A new ICR.*Respondents/Affected Public:*

Individuals and Households.

Total Estimated Number of Annual Responses: 15,300.*Total Estimated Number of Annual Burden Hours:* 518.*Abstract:* The FUTURE Act allows Federal Student Aid to receive customers’ federal tax information (FTI) from the Internal Revenue Service (IRS) through the Internal Revenue Code § 6103 for the purposes of administering the Free Application for Federal Student Aid (FAFSA®) form, and income-driven repayment (IDR) plans. Since customers will be required to provide consent for this process, we also need to provide an option for them to revoke consent. This is a request for a new information collection for the form which will allow individuals to revoke previous consent for FTI for the purposes of administration of title IV, Higher Education Act of 1965, as amended, student financial aid activities. The paper form is an alternative option to the web flow to revoke consent for the IDR application. There has been a change in the burden estimate. The revocation now only applies to IDR forms and the information is collected for no other purpose than to apply the applicants request to the IDR application and to keep it on file for any subsequent requests.

Dated: June 26, 2023.

Kun Mullan,*PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.*

[FR Doc. 2023–13901 Filed 6–29–23; 8:45 am]

BILLING CODE 4000–01–P**DEPARTMENT OF EDUCATION****National Advisory Committee on Institutional Quality and Integrity (NACIQI or Committee)****AGENCY:** Office of Postsecondary Education, U.S. Department of Education.**ACTION:** Announcement of an open meeting.**SUMMARY:** This notice sets forth the agenda, time, and instructions to access or participate in the August 1–3, 2023, virtual meeting of NACIQI, and provides information to members of the public regarding the meeting, including

requesting to make written or oral comments. Committee members will meet in-person while accrediting agency representatives and public attendees will participate virtually.

ADDRESSES: Department of Education, Barnard Auditorium, 400 Maryland Avenue SW, Washington, DC 20202. Only NACIQI members and Department of Education staff will meet at this address.**DATES:** The virtual NACIQI meeting will be held on August 1–3, 2023, from 9:00 a.m. to 5:00 p.m. Eastern Time.**FOR FURTHER INFORMATION CONTACT:** George Alan Smith, Executive Director/ Designated Federal Official (DFO), NACIQI, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202, telephone: (202) 453–7757, or email: George.Alan.Smith@ed.gov.**SUPPLEMENTARY INFORMATION:****Statutory Authority and Function**

NACIQI is established under section 114 of the HEA (20 U.S.C. 1011c). NACIQI advises the Secretary of Education with respect to:

- The establishment and enforcement of the standards of accrediting agencies or associations under subpart 2, part H, Title IV of the HEA, as amended;
- The recognition of specific accrediting agencies or associations;
- The preparation and publication of the list of nationally recognized accrediting agencies and associations;
- The eligibility and certification process for institutions of higher education under Title IV of the HEA, together with recommendations for improvement in such process;
- The relationship between (1) accreditation of institutions of higher education and the certification and eligibility of such institutions, and (2) State licensing responsibilities with respect to such institutions; and
- Any other advisory functions relating to accreditation and institutional eligibility that the Secretary of Education may prescribe by regulation.

The notice of this meeting is required by 5 U.S.C. chapter 10 (Federal Advisory Committees) and section 114(d)(1)(B) of the Higher Education Act of 1965, as amended (HEA).

Virtual Meeting Agenda

The purpose of the virtual meeting is to conduct a review of the applications for renewal of recognition and compliance reports listed below and to present and discuss policy-related matters.

Applications for Renewal of Recognition

1. Association of Advanced Rabbinical and Talmudic Schools, Accreditation Commission. *Scope of Recognition:* The accreditation and preaccreditation (“Correspondent” and “Candidate”) of advanced rabbinical and Talmudic schools to include Associate, Baccalaureate, Masters, Doctorate, and First Rabbinic and First Talmudic degrees programs. *Geographic Area of Accrediting Activities:* Throughout the United States.

2. Academy of Nutrition and Dietetics, Accreditation Council for Education in Nutrition and Dietetics. *Scope of Recognition:* The accreditation and preaccreditation of Didactic and Coordinated Programs in Dietetics at both the undergraduate and graduate level, postbaccalaureate Dietetic Internships, and Dietetic Technician Programs at the associate degree level and for its accreditation of such programs offered via distance education. *Geographic Area of Accrediting Activities:* Throughout the United States.

3. American Optometric Association, Accreditation Council on Optometric Education. *Scope of Recognition:* The accreditation of professional optometric degree programs and optometric residency programs, and for the preaccreditation category of Preliminary Approval for professional optometric degree programs. *Geographic Area of Accrediting Activities:* Throughout the United States.

4. Commission on Collegiate Nursing Education. *Scope of Recognition:* The accreditation of nursing education programs at the baccalaureate, master’s, doctoral, and certificate levels, including programs offering distance education. *Geographic Area of Accrediting Activities:* Throughout the United States.

5. Council on Accreditation of Nurse Anesthesia Educational Programs. *Scope of Recognition:* The accreditation of institutions and programs of nurse anesthesia at the post master’s certificate, master’s, or doctoral degree levels, including programs offering distance education. *Geographic Area of Accrediting Activities:* Throughout the United States.

Requested Scope of Recognition: The accreditation of institutions and programs of nurse anesthesia at the post master’s certificate, post-doctoral certificate, master’s, or doctoral degree levels, including programs offering distance education. *Geographic Area of Accrediting Activities:* Throughout the United States.

6. Liaison Committee on Medical Education. *Scope of Recognition:* The accreditation of medical education programs leading to the M.D. degree. *Geographic Area of Accrediting Activities:* Throughout the United States.

7. National Association of Schools of Art and Design, Commission on Accreditation. *Scope of Recognition:* The accreditation of freestanding institutions and units offering art/design and art/design-related programs (both degree- and non-degree-granting), including those offered via distance education. *Geographic Area of Accrediting Activities:* Throughout the United States.

8. Northwest Commission on Colleges and Universities. *Scope of Recognition:* The accreditation and preaccreditation (“Candidacy status”) of postsecondary degree-granting educational institutions and the accreditation of programs offered via distance education within these institutions. *Geographic Area of Accrediting Activities:* Throughout the United States.

Compliance Reports

1. Commission on Massage Therapy Accreditation. *Scope of Recognition:* The accreditation of institutions and programs that award postsecondary certificates, postsecondary diplomas, academic Associate degrees and occupational Associate degrees, in the practice of massage therapy, bodywork, and aesthetics/esthetics and skin care. *Geographic Area of Accrediting Activities:* Throughout the United States. The compliance report addresses findings of noncompliance with Criteria in 34 CFR part 602, as referenced in the senior Department official’s (SDO) (as defined in 34 CFR 602.3) decision letter dated June 02, 2021, available under NACIQI meeting date February 25, 2021, available at: <https://surveys.ope.ed.gov/erecognition/#/public-documents>.

Military Degree Granting Authority Substantive Change Approval in Accordance With Department of Defense DOD Instruction 5545.04

1. The National Defense University. Name Change of degree program from “Master of Science in Government Information Leadership” to “Master of Science in Strategic Information and Cyberspace Studies.”

To ensure sufficient time for all agency reviews, including NACIQI member questions and discussion, the Department requests that agencies limit the total time of their opening statements to 10 minutes, and that agencies avoid extended discussions about their representatives and

backgrounds. Following the opening statement, the agency’s presentation should focus on regulatory criteria—particularly to responses to areas where the staff has recommended a finding of noncompliance or substantial compliance, or where other concerns have been raised that the agency would like to address. Questions from NACIQI members may focus on other areas.

Administration Policy Update

A representative of the Administration will discuss higher education policy priorities.

Regulations Subcommittee Report

The NACIQI Regulations Subcommittee will present recommendations to the Committee for review and consideration for sharing with the Department in advance of the Department’s upcoming negotiated rulemaking process.

Accreditor Dashboards

A member of the Department staff will provide an update on recent changes to the Accreditor Dashboards.

NACIQI Policy Discussion

In addition to its review of accrediting agencies for Secretarial recognition, there will be time for Committee discussions regarding any of the categories within NACIQI’s statutory authority in its capacity as an advisory committee.

Instructions To Access or Participate in the Virtual Meeting

Accrediting agency representatives and members of the public must access or participate in the meeting virtually.

You must register online at <https://cvent.me/04MvVB> any time before the meeting begins on August 1, 2023.

After you register, you will receive a confirmation email containing personalized participation links for each day of the three-day meeting.

Public Comment

Submission of requests to make an oral comment regarding a specific accrediting agency under review, or to make an oral comment or written statement regarding other issues within the scope of NACIQI’s authority:

The opportunity to submit a written statement regarding a specific accrediting agency under review was solicited by a previous **Federal Register** notice published on May 5, 2022 (87 FR 26743; Document Number 2022–09582). The opportunity to submit written statements regarding the National Defense University (NDU) was solicited by a previous **Federal Register** notice

published on November 14, 2022 (87 FR 68144; Document Number 2022–24637). The periods for submission of such statements are now closed. Additional written statements regarding the specific accrediting agencies and institution under review as identified in this **Federal Register** notice will not be accepted or provided to NACIQI members for purposes of the current cycle of review. However, members of the public may submit written statements regarding other issues within the scope of NACIQI's authority for consideration by NACIQI in the manner described below. Members of the public may also make oral comments regarding the specific accrediting agencies and institution under review, as identified in this **Federal Register** notice, and/or other agenda topics. Oral comments may not exceed three minutes. Oral comments about an agency's recognition when a compliance report has been required by the SDO or the Secretary must relate to the criteria for recognition cited in the SDO's letter that requested the report, or in the Secretary's appeal decision, if any. Oral comments about an agency seeking expansion of scope must be directed to the agency's ability to serve as a recognized accrediting agency with respect to the kinds of institutions or programs requested to be added. Oral comments about the renewal of an agency's recognition must relate to its compliance with the criteria for the Recognition of Accrediting Agencies, which are available at www.ed.gov/admins/finaid/accred/index.html.

Written statements and oral comments concerning NACIQI's work outside of a specific accrediting agency under review must be limited to matters within the scope of NACIQI's authority as outlined under Section 114 of the HEA (20 U.S.C. 1011c). Written statements of any kind submitted after the deadline will not be considered by the Department or provided to NACIQI for purposes of the current cycle of review. Requests to make oral comments that are received outside of the periods noted below will not be accepted.

Instructions on Requesting To Make Public Comment

To request to make oral comments of three minutes or less during the August 1–3, 2023 virtual meeting, please follow Method One or Method Two below. To submit a written statement to NACIQI concerning its work outside of a specific accrediting agency under review, please follow Method One.

Method One: Submit a request by email to the ThirdPartyComments@ed.gov mailbox. Please do not send

material directly to NACIQI members. Written statements to NACIQI concerning its work outside of a specific accrediting agency under review and requests to make oral comment must be received by 5:00pm Eastern Time on July 25, 2023 and include the subject line “Oral Comment Request: (agency name),” “Oral Comment Request: (subject)” or “Written Statement: (subject).” The email must include the name(s), title, organization/affiliation, mailing address, email address, and telephone number, of the person(s) submitting a written statement or requesting to speak. All individuals submitting an advance request in accordance with Method One will be afforded an opportunity to speak. If you intend to make your comments by dialing into the meeting rather than using a computer, please be sure to include that information in your email request.

Method Two (Available only to those seeking to make oral comments): Submit a request by email on August 1, 2023, between 7:45 a.m. to 8:45 a.m. Eastern Time to ThirdPartyComments@ed.gov; requests outside of this period will not be accepted. The email must include the subject line “Oral Comment Request: (agency name),” or “Oral Comment Request: (subject)” on which the requestor wishes to comment, in addition to his or her name, title, organization/affiliation, mailing address, email address, and telephone number. If you intend to make your comments by dialing into the meeting rather than using a computer, please include that information in your email request. For each agenda item, we will allot a total of up to 15 minutes for oral commenters who submit a request in accordance with Method Two. We will select individuals using Method Two on a first-come, first-served basis. If selected, each commenter may not exceed three minutes.

Access to Records of the Virtual Meeting: The Department will post the official report of the virtual meeting on the NACIQI website at <https://sites.ed.gov/naciqi/archive-of-meetings> within 90 days after the meeting. In addition, pursuant to 5 U.S.C. 1009, the public may request to inspect records of the meeting at 400 Maryland Avenue SW, Washington, DC, by emailing aslrecordsmanager@ed.gov or by calling (202) 453–7415 to schedule an appointment. SDO decisions, pursuant to 34 CFR 602.36, associated with all NACIQI meetings are located at the following website: <https://surveys.ope.ed.gov/erecognition/#/public-documents>.

Reasonable Accommodations: The dial-in information and weblink access to the virtual meeting are accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the virtual meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format), notify the contact person in this notice at least two weeks before the meeting. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

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

Authority: Section 114 of the HEA of 1964, as amended (20 U.S.C. 1011c).

Annmarie Weisman,

Deputy Assistant Secretary for Policy, Planning and Innovation, Office of Postsecondary Education.

[FR Doc. 2023–13917 Filed 6–29–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Basic Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces a meeting of the Basic Energy Sciences Advisory Committee (BESAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, July 27, 2023; 11:00 a.m. to 5:00 p.m.

ADDRESSES: This meeting is open to the public. This meeting will be held virtually via Zoom. Information to participate can be found on the website closer to the meeting date at <https://science.osti.gov/bes/besac/Meetings>.

FOR FURTHER INFORMATION CONTACT:

Kerry Hochberger; Office of Basic Energy Sciences; U.S. Department of Energy; Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (301) 903-7661 or Email: kerry.hochberger@science.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of this Board is to make recommendations to DOE-SC concerning the basic energy sciences research program.

Tentative Agenda

- Call to Order, Introductions, Review of the Agenda
- Updates on 2023 BESAC Charges
- Welcome from the Office of Science
- News from the Office of Basic Energy Sciences
- Progress Towards Liquid Solar Fuels
- Defining Strategic Directions for Research
- Basic Research Needs Update
- Update on Computational Chemical and Materials Sciences
- Public Comment
- Adjourn

Breaks taken as appropriate.

Public Participation: The meeting is open to the public. A webcast of this meeting will be available. Please check the website below for updates and information on how to view the meeting. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Kerry Hochberger at kerry.hochberger@science.doe.gov. You must request an oral statement at least five business days before the meeting. Reasonable provisions will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule. Information about the committee can be found at: <https://science.osti.gov/bes/besac>.

Minutes: The minutes of this meeting will be available for review on the U.S. Department of Energy's Office of Basic Energy Sciences website at: <https://science.osti.gov/bes/besac/Meetings>.

Signed in Washington, DC, on June 22, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023-13914 Filed 6-29-23; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Industry Day—Expanding Clean Energy Generation on DOE Lands

AGENCY: U.S. Department of Energy.

ACTION: Notice of Industry Day on Developing Clean Energy Generation on DOE Lands.

SUMMARY: The U.S. Department of Energy (DOE) is launching an initiative to increase clean energy production by making DOE land available for the potential development of new clean electricity generation through leases. To support this effort, DOE is hosting an Industry Day. At the Industry Day, Secretary Granholm will present DOE's vision for utilizing DOE land to achieve clean electricity goals and senior leaders will share information on sites potentially available for development. Participants will have the opportunity to ask questions and provide feedback.

DATES: The Industry Day will be held on Friday, July 28, 2023, from 10:00 a.m. to 2:30 p.m.

ADDRESSES: DOE Headquarters, James V. Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585.

Registration: The Industry Day is open to interested parties with proven experience in implementing successful clean electricity projects generating 200 MW or larger.

Interested participants must register by Wednesday, July 19, 2023 at DOE_Industry_Day@hq.doe.gov and provide their name (as it appears on their government-issued identification), title, organization or company, email address, and telephone number.

Interested participants may also submit questions to DOE_Industry_Day@hq.doe.gov no later than Wednesday, July 19, 2023.

FOR FURTHER INFORMATION CONTACT:

Craig Zamuda, Director of Sustainability Performance Office, Office of Management, U.S. Department of Energy at (202) 586-8645 or craig.zamuda@hq.doe.gov.

SUPPLEMENTARY INFORMATION: DOE has identified land at several of its sites for potential deployment of onsite clean electricity generation or storage projects. The land is suitable for large scale clean electricity projects (e.g., 200MW or larger, or approximately 2,000 contiguous acres or larger).

Through Executive Order (E.O.) 14057, *Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability*, President Biden called on agencies to achieve 100% carbon pollution-free electricity (clean electricity) on a net-annual basis as early as 2030, including 50% 24/7 clean electricity. In accordance the E.O., clean electricity means electrical energy produced from resources that generate no carbon emissions, including marine energy, solar, wind, hydrokinetic (including tidal, wave, current, and thermal), geothermal, hydroelectric, nuclear, renewably sourced hydrogen, and electrical energy generation from fossil resources to the extent there is active capture and storage of carbon dioxide emissions that meets EPA requirements.

The E.O. also directs agencies to facilitate new clean electricity generation and energy storage by authorizing the use of their real property assets, including land, for the development of new clean electricity generation and energy storage through leases to the extent permitted by law. As the federal leader on clean-energy research and development and the steward of more than 2 million acres of land, DOE has both a unique opportunity and clear responsibility to lead and identify creative solutions to achieve the president's mandate.

DOE is acting with urgency to significantly increase onsite clean electricity generation by 2030 while ensuring robust protection for our lands, waters, and biodiversity; ensuring site security; elevating stakeholder and especially Tribal benefits where relevant; and creating good jobs.

DOE is holding the Industry Day to share additional information about this initiative and to identify parties with proven experience in implementing successful clean electricity projects generating 200 MW or larger. Such parties must have the capacity and the resources to construct, own and maintain facilities and infrastructure to generate clean electricity.

During the Industry Day, Secretary Granholm will present DOE's vision for utilizing DOE land to achieve clean electricity goals and senior leaders will share information on sites potentially available for development. In addition, policy and technical issues will be discussed including DOE leasing authorities, National Environmental Policy Act (NEPA) requirements, and transmission challenges. Participants will have the opportunity ask questions and provide feedback.

Signing Authority

This document of the Department of Energy was signed on June 26, 2023, by Ingrid Kolb, Director, Office of Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on June 27, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–13932 Filed 6–29–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY**Agency Information Collection Extension**

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its Financial Assistance Information Collection, OMB Control Number 1910–0400. This information collection request covers information necessary to administer and manage DOE's financial assistance programs.

DATES: Comments regarding this collection must be received on or before July 31, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 881–8585.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular

information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Richard Bonnell by email at richard.bonnell@hq.doe.gov or by telephone (202) 287–1747. Please put “2023 DOE Agency Information Collection Renewal-Financial Assistance” in the subject line when sending an email.

SUPPLEMENTARY INFORMATION: This information collection request contains:

- (1) *OMB No.*: 1910–0400 (Renewal);
- (2) *Information Collection Request Title*: DOE Financial Assistance Information Clearance;
- (3) *Type of Request*: Renewal;
- (4) *Purpose*: This information collection package covers mandatory information collections necessary to annually plan, solicit, negotiate, award, administer, and closeout grants and cooperative agreements under the Department's financial assistance programs. The information is used by Departmental management to exercise management oversight with respect to implementation of applicable statutory and regulatory requirements and obligations. The collection of this information is critical to ensure that the Government has sufficient information to judge the degree to which awardees meet the terms of their agreements; that public funds are spent in the manner intended; and that fraud, waste, and abuse are immediately detected and eliminated;

(5) *Annual Estimated Number of Respondents*: 22,900;

(6) *Annual Estimated Number of Total Responses*: 265,550;

(7) *Estimated Number of Burden Hours*: 1,464,800; and

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: \$81,384,288.

Statutory Authority: Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6301–6308.

Signing Authority

This document of the Department of Energy was signed on June 22, 2023, by John R. Bashista, Director, Office of Acquisition Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for

publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on June 27, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–13931 Filed 6–29–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY**Environmental Management Site-Specific Advisory Board, Savannah River Site**

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Monday, July 24, 2023; 1:00 p.m.–4:15 p.m. EDT. Tuesday, July 25, 2023; 9:00 a.m.–4:00 p.m. EDT.

ADDRESSES: Augusta Technical College—Waynesboro, 216 Highway 24 S, Waynesboro, GA 30830.

The meeting will also be streamed on YouTube, no registration is necessary; links for the livestream can be found on the following website: <https://cab.srs.gov/srs-cab.html>.

FOR FURTHER INFORMATION CONTACT:

Amy Boyette, Office of External Affairs, U.S. Department of Energy (DOE), Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 952–6120; or Email: amy.boyette@srs.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Tentative Agenda

Monday, July 24, 2023

Chair Update

Agency Updates
 Subcommittee Updates
 Program Presentations
 Board Business
 Public Comments

Tuesday, July 25, 2023:

Program Presentations
 Public Comments
 Board Business, Voting

Public Participation: The meeting is open to the public. To provide a safe meeting environment, seating may be limited; attendees should register for in-person attendance by sending an email to srscitizensadvisoryboard@srs.gov no later than 4:00 p.m. EDT on Friday, July 21, 2023. The EM SSAB, Savannah River Site, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Amy Boyette at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board via email either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should submit their request to srscitizensadvisoryboard@srs.gov. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. Comments will be accepted after the meeting, by no later than 4:00 p.m. ET on Tuesday, August 1, 2023. Please submit comments to srscitizensadvisoryboard@srs.gov. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make oral public comments will be provided a maximum of five minutes to present their comments. Individuals wishing to submit written public comments should email them as directed above.

Minutes: Minutes will be available by emailing or calling Amy Boyette at the email address or telephone number listed above. Minutes will also be available at the following website: <https://cab.srs.gov/srs-cab.html>.

Signed in Washington, DC, on June 22, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023-13915 Filed 6-29-23; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TX23-5-000]

THSI bn, LLC; Notice of Filing

Take notice that on June 21, 2023, pursuant to sections 210 and 212 of the Federal Power Act,¹ THSI bn, LLC (THSI) filed an application requesting that the Federal Energy Regulatory Commission (Commission) require Arizona Electric Power Cooperative (AEP) to provide interconnection service to THSI's proposed Three Sisters Solar Project (Three Sisters Project or Project), a solar generation and battery storage project THSI is developing in Cochise, Arizona.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

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://ferc.gov>) using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TTY, (202) 502-8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using

the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Comment Date: 5:00 p.m. Eastern Time on July 12, 2023.

Dated: June 26, 2023.

Debbie-Anne A. Reese,
Deputy Secretary.

[FR Doc. 2023-13975 Filed 6-29-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas & Oil Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP19-78-010.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: Compliance filing: Compliance with 05/26/23 Order-Docket Nos. RP19-78, RP19-1523, and RP19-257 to be effective 3/1/2020.

Filed Date: 6/26/23.

Accession Number: 20230626-5089.

Comment Date: 5 p.m. ET 7/10/23.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

¹ 16 U.S.C. 824i, 824k.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

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Dated: June 26, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023-13977 Filed 6-29-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23-2236-000.

Applicants: Chisholm Trail Solar Energy LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5043.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2237-000.

Applicants: Flat Ridge 4 Wind Holdings LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5045.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2238-000.

Applicants: Flat Ridge 4 Wind, LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5046.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2239-000.

Applicants: HQC Solar Holdings 1, LLC.

Description: Petition for Limited Waiver of HQC Solar Holdings 1, LLC.

Filed Date: 6/20/23.

Accession Number: 20230620-5304.

Comment Date: 5 p.m. ET 7/11/23.

Docket Numbers: ER23-2240-000.

Applicants: Flat Ridge 5 Wind Energy Holdings LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5048.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2241-000.

Applicants: Flat Ridge 5 Wind Energy LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5049.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2242-000.

Applicants: Lazbuddie Wind Energy Holdings LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5050.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2243-000.

Applicants: Lazbuddie Wind Energy LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5052.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2244-000.

Applicants: Pixley Solar Energy Holdings LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5054.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2245-000.

Applicants: Pixley Solar Energy LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5056.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2246-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2023-06-26-TSGT-Const-Finney to Lamar 345 kV-735-0.0.0 to be effective 5/16/2023.
Filed Date: 6/26/23.

Accession Number: 20230626-5062.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2247-000.

Applicants: Energy Prepay I, LLC.

Description: Tariff Amendment:

Cancellation entire tariff to be effective 6/27/2023.

Filed Date: 6/26/23.

Accession Number: 20230626-5069.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2248-000.

Applicants: MS Solar Solutions Corp.

Description: Tariff Amendment:

Cancellation entire tariff to be effective 6/27/2023.

Filed Date: 6/26/23.

Accession Number: 20230626-5073.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2249-000.

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): Lexington Solar + BESS LGIA Filing to be effective 6/15/2023.

Filed Date: 6/26/23.

Accession Number: 20230626-5080.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2250-000.

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): Wrightsville Solar + BESS LGIA Filing to be effective 6/14/2023.

Filed Date: 6/26/23.

Accession Number: 20230626-5081.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2251-000.

Applicants: Central Hudson Gas &

Electric Corporation.

Description: § 205(d) Rate Filing:

Revision to FERC Rate Schedule 202 to be effective 6/13/2023.

Filed Date: 6/26/23.

Accession Number: 20230626-5087.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2252-000.

Applicants: Southwest Power Pool,

Inc.

Description: § 205(d) Rate Filing:

1266R14 Kansas Municipal Energy Agency NITSA and NOA to be effective 9/1/2023.

Filed Date: 6/26/23.

Accession Number: 20230626-5092.

Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: ER23-2253-000.

Applicants: Southern California

Edison Company.

Description: § 205(d) Rate Filing: IA,

Ten West Link Transmission (TOT784/RS FERC NO. 532) to be effective 6/27/2023.

Filed Date: 6/26/23.
Accession Number: 20230626–5093.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2254–000.
Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2562R13 Kansas Municipal Energy Agency NITSA NOA to be effective 9/1/2023.

Filed Date: 6/26/23.
Accession Number: 20230626–5095.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2255–000.
Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3599R2 Missouri Electric Commission NITSA NOA to be effective 9/1/2023.

Filed Date: 6/26/23.
Accession Number: 20230626–5101.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2256–000.
Applicants: AEP Indiana Michigan Transmission Company, Inc., PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: AEP Indiana Michigan Transmission Company, Inc. submits tariff filing per 35.13(a)(2)(iii): AEP and METC submit Second Amended and Restated IA, SA No. 4251 to be effective 6/1/2023.

Filed Date: 6/26/23.
Accession Number: 20230626–5107.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2257–000.
Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: Certificate of Concurrence to Boardman to Hemingway Project Construction Funding to be effective 6/7/2023.

Filed Date: 6/26/23.
Accession Number: 20230626–5108.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2258–000.
Applicants: Southern California Edison Company.

Description: Tariff Amendment: Cancel E&P LA, Ten West Link Transmission (TOT784/SA213) to be effective 6/27/2023.

Filed Date: 6/26/23.
Accession Number: 20230626–5126.
Comment Date: 5 p.m. ET 7/17/23.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but

intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

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Dated: June 26, 2023.

Debbie-Anne A. Reese,
Deputy Secretary.

[FR Doc. 2023–13976 Filed 6–29–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG23–205–000.
Applicants: Algodon Solar Energy Holdings LLC.

Description: Algodon Solar Energy Holdings LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5061.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: EG23–206–000.
Applicants: Algodon Solar Energy LLC.

Description: Algodon Solar Energy LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5063.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: EG23–207–000.
Applicants: Chisholm Trail Solar Energy Holdings LLC.

Description: Chisholm Trail Solar Energy Holdings LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5064.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: EG23–208–000.

Applicants: Flat Ridge 4 Wind, LLC.
Description: Flat Ridge 4 Wind, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5065.
Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: EG23–209–000.
Applicants: Chisholm Trail Solar Energy LLC.

Description: Chisholm Trail Solar Energy LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5066.
Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: EG23–210–000.
Applicants: Flat Ridge 4 Wind Holdings LLC.

Description: Flat Ridge 4 Wind Holdings LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5067.
Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: EG23–211–000.
Applicants: Flat Ridge 5 Wind Energy Holdings LLC.

Description: Flat Ridge 5 Wind Energy Holdings LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5068.
Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: EG23–212–000.
Applicants: Flat Ridge 5 Wind Energy LLC.

Description: Flat Ridge 5 Wind Energy LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5070.
Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: EG23–213–000.
Applicants: Lazbuddie Wind Energy LLC.

Description: Lazbuddie Wind Energy LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.
Accession Number: 20230626–5096.
Comment Date: 5 p.m. ET 7/17/23.

Docket Numbers: EG23–214–000.
Applicants: Pixley Solar Energy Holdings LLC.

Description: Pixley Solar Energy Holdings LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/26/23.

Accession Number: 20230626–5097.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: EG23–215–000.
Applicants: Pixley Solar Energy LLC.
Description: Pixley Solar Energy LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 6/26/23.
Accession Number: 20230626–5099.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: EG23–216–000.
Applicants: Lazbuddie Wind Energy Holdings LLC.
Description: Lazbuddie Wind Energy Holdings LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 6/26/23.
Accession Number: 20230626–5122.
Comment Date: 5 p.m. ET 7/17/23.
 Take notice that the Commission received the following electric rate filings:
Docket Numbers: ER08–1178–000; EL08–88–000.
Applicants: California Independent System Operator Corporation, California Independent System Operator Corporation.
Description: February 2023 through May 2023 Exceptional Dispatch 120 Day Report of the California Independent System Operator Corporation, et al.
Filed Date: 6/26/23.
Accession Number: 20230626–5131.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER10–2564–013; ER10–2600–013; ER10–2289–013.
Applicants: UniSource Energy Development Company, UNS Electric, Inc., Tucson Electric Power Company.
Description: Supplement to December 29, 2021 Triennial Market Power Analysis for Southwest Region of UniSource Energy Development Company, et al.
Filed Date: 6/21/23.
Accession Number: 20230621–5170.
Comment Date: 5 p.m. ET 7/12/23.
Docket Numbers: ER22–69–002.
Applicants: Indeck Niles, LLC.
Description: Notice of Non-Material Change in Status of Indeck Niles, LLC.
Filed Date: 6/23/23.
Accession Number: 20230623–5188.
Comment Date: 5 p.m. ET 7/14/23.
Docket Numbers: ER23–446–002.
Applicants: Duke Energy Indiana, LLC.
Description: Tariff Amendment: DEI—Ameren Services—Amendment of Construction Agreement to be effective 11/17/2022.
Filed Date: 6/26/23.
Accession Number: 20230626–5128.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–1609–001.

Applicants: PJM Interconnection, L.L.C.
Description: Compliance filing: Compliance Filing to Specify Delayed Auction Dates in ER23–1609 to be effective 6/10/2023.
Filed Date: 6/26/23.
Accession Number: 20230626–5119.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2233–000.
Applicants: Algodon Solar Energy Holdings LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.
Accession Number: 20230626–5039.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2234–000.
Applicants: Algodon Solar Energy LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.
Accession Number: 20230626–5040.
Comment Date: 5 p.m. ET 7/17/23.
Docket Numbers: ER23–2235–000.
Applicants: Chisholm Trail Solar Energy Holdings LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization to be effective 8/26/2023.
Filed Date: 6/26/23.
Accession Number: 20230626–5041.
Comment Date: 5 p.m. ET 7/17/23.
 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 or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) 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.
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Dated: June 26, 2023.

Debbie-Anne A. Reese,
 Deputy Secretary.

[FR Doc. 2023–13978 Filed 6–29–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Desert Southwest Region—Rate Order No. WAPA–209

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of proposed formula rates for transmission and firm electric service.

SUMMARY: The Desert Southwest Region (DSW) of the Western Area Power Administration (WAPA) proposes new formula rates for firm and nonfirm point-to-point (P2P) and network integration (Network) transmission service. DSW also proposes to revise the existing formula rates for Parker-Davis Project (PDP) firm electric service (FES) and firm transmission service of Salt Lake City Area/Integrated Projects (SLCA/IP) power. The proposed new formula rates and revisions to existing formula rates would combine the transmission service rates of the Central Arizona Project (CAP), the southern portion of the Pacific Northwest-Pacific Southwest Intertie Project (Intertie), and PDP; and the facilities use charge for the Electrical District No. 5 to Palo Verde Hub Project (ED5–PVH). DSW's proposed formula rates will be effective January 1, 2024, through September 30, 2028. Publication of this **Federal Register** notice begins the formal process for the proposed formula rates.

DATES: The consultation and comment period begins June 30, 2023 and will end September 28, 2023.

DSW will present a detailed explanation of the proposed formula rates and other modifications at a public information forum that will be held on August 7, 2023 from 10 a.m. to no later than 12 p.m. Mountain Standard Time (MST), or until the last comment is received. DSW will host a public comment forum that will be held on August 29, 2023, from 10 a.m. to no later than 12 p.m. MST, or until the last comment is received. The public information forum and the public comment forum will be conducted

virtually. Instructions for participating in the forums will be posted on DSW's website at least 14 days prior to the public information and comment forums at: www.wapa.gov/regions/DSW/Rates/Pages/OTR.aspx.

DSW will accept written comments any time during the consultation and comment period.

ADDRESSES: Written comments and requests to be informed of Federal Energy Regulatory Commission (FERC)

actions concerning the proposed formula rates submitted by WAPA to FERC for approval should be sent to: Jack D. Murray, Regional Manager, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005-6457, or email: dswpwrmrk@wapa.gov. DSW will post information about the proposed formula rates, other changes, and written comments received to its website at:

www.wapa.gov/regions/DSW/Rates/Pages/OTR.aspx.

FOR FURTHER INFORMATION CONTACT: Tina Ramsey, Rates Manager, Desert Southwest Region, Western Area Power Administration, (602) 605-2565 or email: dswpwrmrk@wapa.gov.

SUPPLEMENTARY INFORMATION: FERC approved and confirmed the following Rate Schedules under the applicable Rate Orders on a final basis through the dates indicated below:

Rate schedules	Rate order Nos.	Dates	
		Approval	Expiration
CAP-FT3 ¹	WAPA-193	12/10/2020	12/31/2025
INT-FT5 ²	WAPA-192	3/2/2021	9/30/2023
PD-FT7 ³	WAPA-184	1/31/2019	9/30/2023
CAP-NFT3 ¹	WAPA-193	12/10/2020	12/31/2025
INT-NFT4 ²	WAPA-192	3/2/2021	9/30/2023
PD-NFT7 ³	WAPA-184	1/31/2019	9/30/2023
CAP-NITS3 ¹	WAPA-193	12/10/2020	12/31/2025
INT-NTS4 ⁴	WAPA-200	10/25/2022	9/30/2026
PD-NTS4 ⁴	WAPA-200	10/25/2022	9/30/2026
PD-F7 ³	WAPA-184	1/31/2019	9/30/2023
PD-FCT7 ³	WAPA-184	1/31/2019	9/30/2023

Rate Schedules CAP-FT3, INT-FT5, and PD-FT7 apply to long-term and short-term firm P2P transmission service. Rate Schedules CAP-NFT3, INT-NFT4, and PD-NFT7 apply to nonfirm P2P transmission service. Rate Schedules CAP-NITS3, INT-NTS4, and PD-NTS4 apply to Network transmission service. Rate Schedules PD-F7 and PD-FCT7 apply to PDP FES and transmission service of SLCA/IP power, respectively. Existing rate schedules do not apply to ED5-PVH; rather, since the project began commercial operation in 2015, DSW has charged for the use of ED5-PVH facilities through a contractual arrangement with customers.⁵ The facilities use charge for ED5-PVH is designed to recover all costs incurred by WAPA in connection with the project

including debt service, operation, maintenance, replacements, and extraordinary repairs.

The rates for transmission service on CAP, Intertie, and PDP, and the facilities use charge for ED5-PVH, have substantially converged over the last several years. DSW proposes to combine the rates and charge into "One Transmission Rate" (OTR), which would be applicable to these projects. The OTR would provide benefits to DSW's customers by allowing more efficient scheduling and use of each project's transmission facilities, eliminating multiple charges (rate pancaking) among the transmission systems, and providing rate and financial stability by having a larger revenue requirement and more diverse customer base.

Although the transmission service rates and facilities use charge would be combined under the OTR, the projects will remain separate for financial accounting and repayment purposes. The proposed formula rates under the OTR would provide sufficient revenue to recover annual operation, maintenance, and replacement costs, interest expense, and capital repayment requirements while ensuring repayment of the projects within the cost recovery criteria set forth in Department of Energy (DOE) Order RA 6120.2.

To implement the OTR, DSW is proposing new rate schedules containing formula rates for firm and nonfirm P2P and Network transmission

service. These new schedules will supersede the existing rate schedules for CAP, Intertie, and PDP transmission service and replace the contractual charge for the use of ED5-PVH facilities. DSW also proposes to make changes to the existing formula rates for PDP FES and firm transmission service of SLCA/IP power so they align with the new proposed rate schedule for firm P2P transmission service.

DSW's proposed formula rates for firm and nonfirm P2P and Network transmission service under the OTR, along with PDP FES and firm transmission service of SLCA/IP power, would go into effect on January 1, 2024, and remain in effect through September 30, 2028, or until DSW changes the formula rates through another public rate process pursuant to 10 CFR part 903, whichever occurs first. Since Rate Schedules INT-FT5, PD-FT7, INT-NFT4, PD-NFT7, PD-F7, and PD-FCT7 expire on September 30, 2023, DSW has initiated a separate rate action to extend these rate schedules to provide time to complete the public process for the OTR.

Firm Point-to-Point Transmission Service

DSW proposes a new rate schedule, DSW-FT1, for long-term and short-term firm P2P transmission service on CAP, Intertie, PDP, and ED5-PVH. This new rate schedule will contain formulas to calculate the rates for firm P2P transmission service. For long-term

¹ Order Confirming and Approving Rate Schedules on a Final Basis, Docket No. EF20-10-000.

² Order Confirming and Approving Rate Schedules on a Final Basis, Docket No. EF20-9-000.

³ Order Confirming and Approving Rate Schedules on a Final Basis, Docket No. EF19-1-000.

⁴ Order Confirming and Approving Rate Schedules on a Final Basis, Docket No. EF21-6-000.

⁵ The ED5-PVH is a 109-mile transmission project completed under WAPA's Transmission Infrastructure Program (TIP). TIP was established to implement Section 402 of the American Recovery and Reinvestment Act and manage WAPA's \$3.25 billion borrowing authority to support projects facilitating the delivery of renewable resources in the western United States. Public Law 111-5 (Feb. 17, 2009).

transmission service (one year or longer), the annual rate for each kilowatt per year (kW-year) will be equal to the combined annual transmission revenue requirement (ATRR) of each project, which is the amount of revenue that each project needs to cover the costs associated with its transmission system, divided by the combined anticipated long-term capacity reservations for each project, rounded to the nearest 12-cent increment. For short-term transmission service (up to one year), the maximum rate for each kilowatt will be equal to the annual long-term rate divided by the applicable period of time (*i.e.*, monthly, weekly, daily and hourly) and rounded to five decimal places.

These long-term and short-term rates will be calculated annually using updated financial and capacity reservation information, as applicable. This new rate schedule will supersede Rate Schedules CAP-FT3, INT-FT5, and PD-FT7.

Nonfirm Point-to-Point Transmission Service

DSW proposes a new rate schedule, DSW-NFT1, for nonfirm P2P transmission service on CAP, Intertie, PDP, and ED5-PVH. This new rate schedule will contain a formula to calculate the rate for nonfirm P2P transmission service. The nonfirm rate will be calculated by dividing the annual long-term rate for firm P2P transmission service by 8,760 hours and rounding to five decimal places. The rate will be calculated annually using updated information, as applicable. This new rate schedule will supersede Rate Schedules CAP-NFT3, INT-NFT4, and PD-NFT7.

Network Transmission Service

DSW proposes a new rate schedule, DSW-NTS1, for Network transmission service on CAP, Intertie, PDP, and ED5-PVH. This new rate schedule will contain a formula to calculate the monthly charge for Network transmission service. The monthly charge will be determined by multiplying the customer's load ratio share, the ratio of the customer's network load to the transmission provider's total load, times one twelfth ($\frac{1}{12}$) of the combined ATRR of each project. The combined ATRR will be calculated annually using updated financial information. This new rate schedule will supersede Rate Schedules CAP-NITS3, INT-NTS4, and PD-NTS4.

PDP Firm Electric Service

DSW proposes to revise Rate Schedule PD-F7 so the transmission charge aligns with the proposed new

rate schedule, DSW-FT1, for long-term and short-term firm P2P transmission service on CAP, Intertie, PDP, and ED5-PVH. No changes are being proposed to the energy or capacity charges. DSW also proposes to make other minor changes to Rate Schedule PD-F7. Specifically, the rate schedule will be modified to indicate that recently approved Rate Schedule DSW-UU1⁶ will apply to unauthorized transmission overruns. In addition, the section on transmission losses will be deleted because it only pertained to deliveries made with meters located at distribution voltage, a situation that no longer exists for DSW. The revised rate schedule, PD-F8, will supersede PD-F7.

PDP Transmission Service of SLCA/IP Power

DSW proposes to revise Rate Schedule PD-FCT7 to align with the proposed new rate schedule, DSW-FT1, for long-term and short-term firm P2P transmission service on CAP, Intertie, PDP, and ED5-PVH. DSW also proposes to make minor changes to sections of Rate Schedule PD-FCT7 addressing adjustment for losses and overrun of capacity. Specifically, the new rate schedule will be modified to reflect that recently approved Rate Schedules DSW-TL1 and DSW-UU1⁷ will apply to transmission losses service and unreserved use, respectively. The revised rate schedule, PD-FCT8, will supersede PD-FCT7.

Table of Rate Schedules

The table below provides a crosswalk from the existing rate schedules to the proposed rate schedules.

RATE SCHEDULES

Existing	Proposed
CAP-FT3, INT-FT5 & PD-FT7.	DSW-FT1.
CAP-NFT3, INT-NFT4 & PD-NFT7.	DSW-NFT1.
CAP-NITS3, INT-NTS4 & PD-NTS4.	DSW-NTS1.
PD-F7	PD-F8.
PD-FCT7	PD-FCT8.

Prepayment of Service

DSW proposes long-term firm P2P and Network transmission service under Rate Schedules DSW-FT1 and DSW-NTS1 be prepaid one month in advance and credited in a subsequent month. The Intertie and PDP long-term firm P2P transmission customers currently

prepay for service and will experience no change. As discussed below, CAP long-term firm P2P and PDP Network transmission customers and ED5-PVH facilities use customers will start prepaying for service when the rate schedules become effective.

The monthly prepayment for long-term firm P2P transmission service will be based on the capacity reserved. The monthly prepayment for Network transmission service will be based on the most recent bill. Since transmission customers that currently do not prepay for service will have two payments each month during the first two months, one for service in arrears and one for prepayment, DSW proposes an optional four-month transitional period to phase in prepayments. With a transitional period, the two additional payments that are necessary during the first two months will be evenly distributed over the first four months to help mitigate the potential financial burden on customers.

Legal Authority

Existing DOE procedures for public participation in power and transmission rate adjustments (10 CFR part 903) were published on September 18, 1985, and February 21, 2019.⁸ The proposed action constitutes a major rate adjustment, as defined by 10 CFR 903.2(d). In accordance with 10 CFR 903.15(a) and 10 CFR 903.16(a), DSW will hold public information and public comment forums for this rate adjustment. DSW will review and consider all timely public comments at the conclusion of the consultation and comment period and adjust the proposal as appropriate. The formula rates will then be approved on an interim basis.

WAPA is establishing the formula rates for transmission and firm electric service in accordance with section 302 of the DOE Organization Act (42 U.S.C. 7152).⁹

By Delegation Order No. S1-DEL-RATES-2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to WAPA's Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place

⁸ 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

⁹ This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)); and other acts that specifically apply to the projects involved.

⁶ Order Confirming and Approving Rate Schedules on a Final Basis, FERC Docket No. EF21-6-000.

⁷ Ibid.

into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2023, effective April 10, 2023, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator.

Availability of Information

All brochures, studies, comments, letters, memorandums, or other documents that DSW initiates or uses to develop the proposed formula rates are available on WAPA's website at www.wapa.gov/regions/DSW/Rates/Pages/OTR.aspx.

Ratemaking Procedure Requirements Environmental Compliance

WAPA is in the process of determining whether an environmental assessment or an environmental impact statement should be prepared or if this action can be categorically excluded from those requirements.¹⁰

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on June 5, 2023, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

¹⁰ In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321–4347; the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

Signed in Washington, DC, on June 27, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–13974 Filed 6–29–23; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0273; FRL–11117–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Consolidated Pesticide Registration Submission Portal (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Consolidated Pesticide Registration Submission Portal, (EPA ICR Number 2624.01 and OMB Control Number 2070–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** on August 13, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments must be received on or before July 31, 2023.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OPP–2020–0273, to EPA online using www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. 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.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information

collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Carolyn Siu, Office of Program Support (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1205; email address: siu.carolyn@epa.gov.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. 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.

Public comments were previously requested via the **Federal Register** on August 13, 2020, during a 60-day comment period (85 FR 49366). This notice allows for an additional 30 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 <http://www.epa.gov/dockets>.

Abstract: This new ICR consolidates the collection activities and related burdens currently contained in eight ICRs that are approved by OMB under the PRA. The OMB Terms of Clearance for several of the existing ICRs directed EPA to consolidate these ICRs to simplify the burden presentation and calculations for the public due to the shared or anticipated collection method involving submissions via the Pesticide Submission Portal in EPA's Central Data Exchange (CDX). This consolidation is expected to clarify the capabilities of the Pesticide Submission Portal for respondents and will streamline the activities related to tracking the ICR renewal activities for both the public and EPA.

The new ICR covers the EPA pesticide registration collection activities supporting the statutorily mandated pesticide registration program under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including the activities associated with pesticide registration; pesticide use; pesticide sale and distribution; pesticide permitting

activities; determinations regarding whether a product must be regulated under FIFRA; and pesticide tolerances under the FFDCA.

Form numbers: 8570–1, 8570–4, 8570–5, 8570–17, 8570–25, 8570–27, 8570–34, 8570–35, 8570–36 and 8570–37.

Respondents/affected entities: Pesticide and other agricultural chemical manufacturing, research, and development in the physical, engineering, and life sciences, biological products (except diagnostic) manufacturing, colleges, universities, and professional schools, farm supplies wholesalers, flower, nursery stock, and florist's supplies wholesalers, state government, other chemical and allied product merchant wholesalers, exterminating and pest control service, management, scientific, and technical consulting services.

Respondent's obligation to respond: Mandatory under FIFRA and FFDCA.

Estimated number of respondents: 5,435 (total).

Frequency of response: On occasion.

Total estimated burden: 2,175,048 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$183,517,210 (per year), which includes \$0 annualized capital or operation & maintenance costs.

Changes in the estimates: This information collection combines the burdens from eight previously approved ICRs. The total combined respondent burden hours from those previously approved ICRs by OMB were estimated at 2,175,048 hours, the same amount requested for this ICR.

The total combined cost burden from these eight previously approved ICRs was \$170,250,338. The total cost burden requested for this ICR is \$183,157,210—a increase of \$12,906,872. The difference between the current cost burden request and the previously approved requests is due only to adjustments in EPA's estimates of the wage rates and material costs that were revised to reflect 2022 dollars for this ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023–13944 Filed 6–29–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2004–0077; FRL–11115–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Significant New Alternatives Policy (SNAP) Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Significant New Alternatives Policy (SNAP) Program (EPA ICR Number 1596.11, OMB Control Number 2060–0226) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through August 31, 2023. Public comments were previously requested via the **Federal Register** on January 24, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before July 31, 2023.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2004–0077, to EPA online using www.regulations.gov (our preferred method), by email to a-and-r-docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. 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.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Christina Thompson, Stratospheric Protection Division, Office of Atmospheric Protection, (Mail Code

6205A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–0983; email address: thompson.christina@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through August 31, 2023. 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. Public comments were previously requested via the **Federal Register** on January 24, 2023 during a 60-day comment period (88 FR 4177). This notice allows for an additional 30 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 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 <http://www.epa.gov/dockets>.

Abstract: This information collection is necessary to implement the requirements of the Significant New Alternatives Policy (SNAP) program for evaluating and regulating substitutes for ozone-depleting substances (ODS) being phased out under the stratospheric ozone protection provisions of the Clean Air Act (CAA) and globally under the *Montreal Protocol on Substances that Deplete the Ozone Layer*. Under CAA section 612, EPA is authorized to identify and restrict the use of substitutes for class I and class II ODS (listed in 40 CFR part 82, subpart A, appendices A and B) where EPA determines other alternatives are available or potentially available that reduce overall risk to human health and the environment. Any producer of a new substitute must submit a notice of intent to introduce a substitute into interstate commerce 90 days prior to such introduction. The producer must also provide EPA with information covering a wide range of health and environmental factors. The EPA SNAP program then reviews proposed substitutes based on established risk-assessment criteria and procedures set forth in associated regulations. Results are published in updated lists of acceptable and unacceptable substitutes sorted by end-use categories.

Responses to the collection of information are mandatory under section 612 for anyone who sells or, in certain cases, uses substitutes for an

ODS after April 18, 1994. Measures to protect confidentiality of information collected under the SNAP program are based on EPA's confidentiality regulations (40 CFR 2.201 *et seq.*, or subpart B). Submitters may designate all or portions of their forms or petitions as confidential. EPA requires the submitters to substantiate their claim of confidentiality. Under CAA section 114(c), emissions information may not be claimed as confidential.

Any substitute which is a new chemical must also be submitted to the Agency under the New Chemicals (Premanufacture Notice) program under the Toxic Substances Control Act (TSCA). Furthermore, alternatives that will be used as sterilants must be filed jointly with EPA's Office of Pesticide Programs and with SNAP.

Form Numbers: 1264–14; 1265–14.

Respondents/affected entities:

Manufacturers, importers, formulators, and processors of substitutes for ODS.

Respondent's obligation to respond: Mandatory (40 CFR 82.176).

Estimated number of respondents: 154 (per year).

Frequency of response: Annual.

Total estimated burden: 4,855 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$444,249, which includes \$22,912 annualized capital or operation & maintenance costs.

Changes in the Estimates: The number of SNAP submissions each year is expected to remain the same from the previous ICR, at an average of 15 per year during the next 3 years. In 2020 the Agency received 20 new SNAP submissions, and in 2021 the Agency received 13 submissions. In the first 10 months of 2022, the Agency received 6 submissions, although multiple submissions applied for more than 5 end-uses. Many of the recent SNAP submissions, and those anticipated over the next three years, are for chemicals previously found acceptable for other SNAP applications or for blends of alternatives already found acceptable. The burden of developing supporting information for the majority of these submissions is expected to decrease because it is easier to find and review information for substitutes that have been reviewed previously.

There is an estimated 20% reduction in the number of respondents responsible for recordkeeping for substitutes acceptable subject to use conditions and narrowed use limits. This reduction is expected because the increased availability of alternatives decreases the need for industry to use alternatives previously listed as

acceptable subject to narrowed use limits.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023–13958 Filed 6–29–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–075]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or <https://www.epa.gov/nepa>.

Weekly receipt of Environmental Impact Statements (EIS)

Filed June 16, 2023 10 a.m. EST

Through June 26, 2023, 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search>.

EIS No. 20230078, Draft, NSA, MD, O'Brien Road Access Modernization, Comment Period Ends: 08/14/2023, Contact: Jeffrey Williams 301–688–2970.

EIS No. 20230079, Draft, USAF, CA, KC–46A Main Operating Base Beddown, Comment Period Ends: 08/14/2023, Contact: Austin Naranjo 478–222–9225.

EIS No. 20230080, Final, USN, VA, Disposal of Decommissioned, Defueled Ex-Enterprise (CVN 65) and its Associated Naval Reactor Plants, Review Period Ends: 07/31/2023, Contact: Amanda Stuhldreher 202–781–6368.

EIS No. 20230081, Draft Supplement, USPS, DC, Draft Supplemental Environmental Impact Statement for Next Generation Delivery Vehicle Acquisitions, Comment Period Ends: 08/14/2023, Contact: Davon Collins 202–268–4570.

Dated: June 26, 2023.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2023–13926 Filed 6–29–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0068; FRL–11125–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; NSPS for VOC Emissions From Petroleum Refinery Wastewater Systems (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for VOC Emissions from Petroleum Refinery Wastewater Systems (EPA ICR Number 1136.14, OMB Control Number 2060–0172) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through August 31, 2023. Public comments were previously requested via the **Federal Register** on July 22, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. **DATES:** Comments may be submitted on or before July 31, 2023.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0068, to EPA online using www.regulations.gov (our preferred method), by email to a-and-r-Docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. 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.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this specific information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Muntasir Ali, Sector Policies and Program Division (D243–05), Office of

Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541-0833; email address: ali.muntasir@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through April 30, 2023. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displayed a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on April 29, 2022 during a 60-day comment period (85 FR 23825). This notice allows for an additional 30 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 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 <http://www.epa.gov/dockets>.

Abstract: The New Source Performance Standards (NSPS) for VOC Emissions from Petroleum Refinery Wastewater Systems (40 CFR part 60, subpart QQQ) were proposed on May 4, 1987; and promulgated on November 23, 1988. These regulations apply to existing facilities and new wastewater systems at petroleum refineries, and cover individual drain systems, oil-water separators, and aggregate facilities. An individual drain system consists of all process drains connected to the first downstream junction box. An oil-water separator is the wastewater treatment equipment used to separate oil from water. An aggregate facility is an individual drain system together with ancillary downstream sewer lines and oil-water separators, down to and including the secondary oil-water separator, as applicable. Aggregate facilities are intended to capture any potential VOC emissions within the petroleum refinery wastewater system during expansions of and additions to the system. New facilities include those that commenced construction, modification, or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 60, subpart QQQ.

In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They

are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NSPS.

Form Numbers: None.

Respondents/affected entities:

Existing and new wastewater systems at petroleum refineries.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart QQQ).

Estimated number of respondents: 130 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 8,900 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$1,340,000 (per year), which includes \$16,900 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: The adjustment decrease in burden from the most recently approved ICR is due to a decrease in the number of sources. The previous ICR included 149 respondents, while this ICR only includes 130. Petroleum refinery capacities have been declining since 2020, including the associated wastewater systems. This ICR estimated the number of respondents using data collected by the U.S. Energy Information Administration. The decrease in the number of sources also led to a decrease of the Capital and Operation & Maintenance costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023-13951 Filed 6-29-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2016-0094; FRL-11120-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Importation of On-Highway Vehicles and Motorcycles and Nonroad Engines, Vehicles, and Equipment (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an

information collection request (ICR), "Importation of On-highway Vehicles and Motorcycles and Nonroad Engines, Vehicles, and Equipment" (EPA ICR Number 2583.03, OMB Control Number 2060-0717) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through June 30, 2023. Public comments were previously requested via the **Federal Register** on October 5, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Additional comments may be submitted on or before July 31, 2023.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OAR-2016-0094, to EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. 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.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Holly Pugliese, Compliance Division, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan, 48105; telephone number: 734-214-4288; fax number: 734-214-4869; email address: pugliese.holly@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through June 30, 2023. 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.

Public comments were previously requested via the **Federal Register** on October 5, 2022, during a 60-day

comment period (87 FR 60392). This notice allows for an additional 30 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 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>.

Abstract: The Clean Air Act requires that on-highway vehicles and motorcycles, and nonroad vehicles, engines, and equipment imported into the U.S. either comply with applicable emission requirements or qualify for an applicable exemption or exclusion. The Compliance Division (CD) in the EPA's Office of Air and Radiation maintains and makes available instruments to importers to help facilitate the importation of products at U.S. Borders. EPA Form 3520-1 is used by importers of on-highway vehicles and motorcycles, and EPA Form 3520-21 is used by importers of nonroad vehicles, engines, and equipment. For most imports, U.S. Customs and Border Protection (CBP) regulations require that EPA Declaration Forms 3520-1 and 3520-21 be filed with CBP at the time of entry. EPA does not require that the forms be submitted directly to EPA. Rather, they are used by CBP to facilitate the importation process at U.S. borders. EPA does require that the forms be kept by importers for a period of five years after importation to assist EPA's Office of Enforcement and Compliance Assurance (OECA) and CBP should any issues arise with any given importation.

In addition, this ICR covers the burden of EPA Form 3520-8 which EPA makes available upon request and is used by Independent Commercial Importers (ICIs), who bring on-highway vehicles into compliance and provide emissions test results, to request final importation clearance for their on-highway vehicles.

Since 2016, CBP has been using the Automated Commercial Environment (ACE) to facilitate the electronic filing of imports documents rather than collecting paper. ACE has become the primary system through which the trade community and other importers report imports and exports. Through ACE as the single point of submission, manual processes have been streamlined and automated, and paper submissions (e.g. fillable PDFs) have been significantly reduced. Rather than file hard copy forms, importers can log into ACE and

check boxes corresponding to information elements currently on the forms. Filers using the ACE interface will also receive transaction information that will be kept by the filer. However, EPA will continue to maintain the forms on our website in fillable PDF format. Although importers are expected to use the ACE interface to submit information, the PDF versions of the form can also be submitted directly into ACE by importers.

Form Numbers: 3520-1, 3520-21, 3520-8.

Respondents/affected entities: Information collected is from individual importers, or companies who import and/or manufacture on-highway vehicles and motorcycles and nonroad engines, vehicles, and equipment.

Respondent's obligation to respond: Required for any importer to legally import on-highway vehicles and motorcycles and nonroad engines, vehicles, and equipment vehicles or engines into the U.S.

Estimated number of respondents: 14,810.

Frequency of response: Once per entry. (One form per shipment may be used.)

Total estimated burden: 131,985 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$8,009,549 (per year), which includes \$0 annualized capital or operation & maintenance costs.

Changes in Estimates: There is an increase of 50,000 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to the estimated annual number of entries (forms filed with CBP) rising from 160,000 per year to approximately 260,000 per year. Accordingly, due to the additional forms filed and slight increases in labor costs, estimated average annual costs have increased by approximately \$3,764,850.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023-13949 Filed 6-29-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2013-0721; FRL-11118-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Chemical Data Reporting Under the Toxic Substances Control Act (TSCA) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Chemical Data Reporting under the Toxic Substances Control Act (TSCA) (EPA ICR Number 1884.15; OMB Control Number 2070-0162), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through June 30, 2023. Public comments were previously requested via the **Federal Register** on September 21, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Additional comments may be submitted on or before July 31, 2023.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OPPT-2013-0721 to EPA online using www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2821T, 1200 Pennsylvania Ave. 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.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Regulatory Support Branch (7602M), Office of Chemical

Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566-1204; email address: sleasman.katherine@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR which is currently approved through June 30, 2023. 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.

Public comments were previously requested via the **Federal Register** on September 21, 2021 during a 60-day comment period (86 FR 52547). This notice allows for an additional 30 days for public comments. Supporting documents which explain in detail the information that the EPA will be collecting are available in the docket for this ICR. The docket can be viewed online at 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>.

Abstract: This information collection request addresses the paperwork requirements contained in the TSCA Chemical Data Reporting (CDR) rule. Under TSCA section 8(a), EPA is authorized to collect certain information on chemical substances manufactured (including imported) or processed in the United States. The CDR collection provides chemical manufacture, processing, and use information that helps EPA identify what chemicals the public may be exposed to as consumers or in commercial and industrial settings. The data also help EPA assess routes of potential exposure to those chemicals. Beginning in 1986, EPA has used the CDR rule eight times to collect basic manufacturing information for selected chemical substances on the TSCA Inventory. More recent collections, beginning in 2006, included additional information relating to the manufacture, processing, and use of those chemical substances. The reporting requirements have been modified through rulemaking, with the most recent major changes occurring in 2020. The 2020 revisions included a phase-in approach for some of its provisions. All provisions will be fully implemented for the 2024 CDR reporting cycle. The changes are described on EPA's CDR web page, at: [https://www.epa.gov/chemical-datareporting/summary-](https://www.epa.gov/chemical-datareporting/summary-reportingrequirement-changes-due-cdr-revisionsand-small)

[reportingrequirement-changes-due-cdr-revisionsand-small](https://www.epa.gov/chemical-datareporting/summary-reportingrequirement-changes-due-cdr-revisionsand-small).

The CDR collection is on a four-year reporting cycle and contains detailed manufacturing, processing, and use information drawn from the principal reporting year; the rule also contains basic information on production volume, by year, for the three years prior to the principal reporting. Individual sites manufacturing (including importing) chemical substances will submit the required information. The information will be stored electronically for reference by EPA staff and others. Within the constraints of confidentiality claims, the information will be made public through the Agency's website: <https://www.epa.gov/chemical-datareporting>. Further discussion on how the information is used, stored, and collected is included in this document.

Form Numbers: Form U (Form #: 9600-010), Form U Primary Manufacturer Import (Form #: 9600-011), Form U Primary Co-Manufacturer Contracting (Form #: 9600-012), Form U Primary Co-Manufacturer Producing (Form #: 9600-013), Form U Secondary or Tertiary (Form #: 9600-014), and Form U Secondary Notifying Tertiary (Form #9600-015).

Respondents/affected Entities: Potentially affected entities may include but are not limited to the following: 325 Chemical Manufacturing and 324 Petroleum and Coal Product Manufacturing.

Respondent's obligation to respond: Mandatory, TSCA section 8(a) and 40 CFR part 711.

Estimated number of respondents: 5,460 (total).

Frequency of response: Every four years.

Total estimated burden: 729,465 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$78,616,166 (per year), which includes \$0 annualized capital or operation & maintenance costs.

Changes in the estimates: There is an increase of 10,194 hours in the total estimated burden compared with that currently approved by OMB. This increase reflects a combination of reporting requirement changes including changes to the information reported (+35,611 hours) and changes to the number of reporters (-25,417 hours) due to byproducts exemptions and a new small manufacturer definition, which were included in two ICR addendums approved by OMB in 2020 (one associated with the 2020 CDR

Revisions Rule and the other with the 2020 8(a) SMD Update Rule).

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023-13948 Filed 6-29-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-AO-2022-0729; FRL-11124-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Environmental Education Local Grants Progress Report Form (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Environmental Education Local Grants Progress Report Form (EPA ICR Number 2731.01, OMB Control Number 2090-NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** on November 15, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before July 31, 2023.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA-HQ-AO-2022-0729, to EPA online using www.regulations.gov (our preferred method), by email to docket_oms@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. 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.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public

Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Michael Band, Office of Environmental Education, (1704A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-564-3155; email address: band.michael@epa.gov.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. 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.

Public comments were previously requested via the **Federal Register** on November 15, 2022, during a 60-day comment period (87 FR 68482). This notice allows for an additional 30 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 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 <http://www.epa.gov/dockets>.

Abstract: This notice announces the collection of information related to the U.S. EPA Environmental Education (EE) Local Grants Program. EPA proposes to collect information from this program’s grant recipients. Specifically, EPA proposes to have all EE grantees use the progress report form, detailed in the supporting statement, when drafting their Quarterly Progress Reports and Final Reports. By requiring all EE Grantees to use the EE Local Grant Progress Report Form, EPA’s Office of Environmental Education will be equipped to gather data on this grant program’s outputs, outcomes, the total number of individuals reached, and the total number of underserved communities reached. This information will help EPA ensure projects are on schedule to meet their goals and produce high-quality environmental outputs. Additionally, requiring all EE grantees to submit their Quarterly and Final reports using the proposed form will allow EPA’s Office of Environmental Education to accurately track and report the overall impact of this grant program as well as contribute to the Agency’s Justice40 reporting requirements.

Form Numbers: EPA Form Number 5800-082.

Respondents/affected entities: Local education agencies, colleges or universities, state education or environmental agencies, nonprofit organizations as described in Section 501(C)(3) of the U.S. Internal Revenue Code, noncommercial educational broadcasting entities as defined and licensed by the U.S. Federal Communications Commission.

Respondent’s obligation to respond: Mandatory (in accordance with OMB and EPA regulations, title 2 CFR, parts 200 and 1500, the recipient agrees to submit progress reports on a quarterly basis to the EPA Project Officer within thirty (30) days after each reporting period and the Final Report to the EPA Project Officer within one hundred twenty (120) days after the expiration or termination of the approved project period.

Estimated number of respondents: 240 (per year).

Frequency of response: Four times per year for the Quarterly Progress Reports; one time for the Final Report.

Total estimated burden: 800 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$53,664 (per year), includes \$0 annualized capital or operation & maintenance costs.

Changes in Estimates: This is a new collection. Over time, the Office of Environmental Education expects the burden numbers to decrease due to increased access to technology.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023-13950 Filed 6-29-23; 8:45 am]

BILLING CODE 6560-50-P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Thursday, July 13, 2023.

PLACE: You may observe the open portions of this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102-5090, or virtually. If you would like to observe, at least 24 hours in advance, visit [FCA.gov](https://www.fca.gov), select “Newsroom,” then select “Events.” From there, access the linked “Instructions for board meeting visitors” and complete the described registration process.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The following matters will be considered:

PORTIONS OPEN TO THE PUBLIC:

- Approval of Minutes for June 8, 2023

PORTIONS CLOSED TO THE PUBLIC:

- Agency and Farm Credit System Cybersecurity and Privacy Risk Update¹

CONTACT PERSON FOR MORE INFORMATION:

If you need more information or assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703-883-4009. TTY: 703-883-4056.

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2023-14068 Filed 6-28-23; 4:15 pm]

BILLING CODE 6705-01-P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 151654]

Privacy Act of 1974; System of Records.

AGENCY: Federal Communications Commission.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Communications Commission (FCC, Commission, or Agency) has modified an existing system of records, FCC/EB-5, Enforcement Bureau Activity Tracking System (EBATS), subject to the Privacy Act of 1974, as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the agency. The FCC’s Enforcement Bureau (EB) uses EBATS to track its investigations into possible violations of Federal communications laws and regulations. This modification updates the applicable records retention and disposal schedule; updates the language, including section headers, in this SORN to be consistent with the general language currently used in FCC SORNs as well as recommendations by current OMB guidance and administrative changes; makes minor clerical corrections; adds two routine uses; deletes two routine uses; and updates seven routine uses.

DATES: This action will become effective on June 30, 2023. The routine uses in this action will become effective on July 31, 2023 unless comments are received that require a contrary determination.

ADDRESSES: Send comments to Katherine C. Clark, Attorney-Advisor,

¹ Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8), and (9).

Office of General Counsel, Room 10.306, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, or to Privacy@fcc.gov.

FOR FURTHER INFORMATION CONTACT:

Katherine C. Clark, (202) 418–1773 or Privacy@fcc.gov (and to obtain a copy of the Narrative Statement and the Supplementary Document, which includes details of the proposed alterations to this system of records).

SUPPLEMENTARY INFORMATION: This notice serves to update and modify FCC/EB–5, as a result of various necessary changes and updates. The substantive changes and modifications to the previously published version of the FCC/EB–5 system of records include:

1. Updating the language in the Security Classification to follow OMB guidance;
2. Updating the System Location to note that records are maintained primarily at FCC Headquarters in Washington, DC, and only on an *ad hoc*, temporary basis at FCC field offices when needed to resolve enforcement cases in their jurisdictions;
3. Updating the language in the Purposes section to be consistent with the language and phrasing currently used generally in the FCC's SORNs and to include maintaining documents and tracking the status of formal complaints, including, but not limited to those that involve market disputes as an additional purpose for the system;
4. Modifying the language in the Categories of Individuals and Categories of Records to be consistent with the language and phrasing currently used in the FCC's SORNs;
5. Updating and/or revising language in seven routine uses (listed by current routine use number): (1) Public Access; (3) FCC Enforcement Actions; (4/5) Adjudication and Litigation (now two separate routine uses); (6) Law Enforcement and Investigation; (7) Congressional Inquiries; (8) Government-wide Program Management and Oversight; and (9) Breach Notification, the revision of which is as required by OMB Memorandum No. M–17–12;
6. Deleting the following routine uses (listed by former routine use number): (2) Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by the Agency; and (3) Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by an Entity other than the Agency;
7. Adding two new routine uses (listed by current routine use number): (10) Assistance to Federal Agencies and

Entities Related to Breaches, which is required by OMB Memorandum No. M–17–12; and (11) Non-Federal Personnel to allow contractors, grantees, or volunteers performing or working on a contract, grant, or cooperative agreement for the Federal Government to have access to needed information;

8. Updating the existing records retention and disposal schedule with a new records schedule, Records Disposition Authority, DAA–0173–2014–0002, which was approved by NARA in September 2015;

9. Updating the reference to the exemptions claimed under subsection (k) of the Privacy Act; and

10. Updating the notice to reflect various administrative changes related to the system managers and system addresses; policy and practices for storage and retrieval of the information; administrative, technical, and physical safeguards; and updated notification, records access, and contesting records procedures.

SYSTEM NAME AND NUMBER:

FCC/EB–5, Enforcement Bureau Activity Tracking System (EBATS).

SECURITY CLASSIFICATION:

No information in the system is classified.

SYSTEM LOCATION:

Enforcement Bureau (EB), FCC, 45 L Street NE, Washington, DC 20554; and FCC Field Offices that may maintain paper documents on an *ad hoc*, temporary basis when needed to resolve enforcement cases in their jurisdictions.

SYSTEM MANAGER(S):

Enforcement Bureau (EB), FCC, 45 L Street NE, Washington, DC 20554.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

47 U.S.C. 101, 102, 104, 301, 303, 309(e), 312, 315, 318, 362, 364, 386, 501, 502, 503, 507, and 510.

PURPOSE(S) OF THE SYSTEM:

The Enforcement Bureau uses the information in this system for purposes that include, but are not limited to:

1. Maintaining documents and tracking the status of enforcement investigations of entities (including individuals) that have been identified as possible violators of the Communications Act of 1934, as amended, FCC regulations, other FCC requirements or orders, other statutes and regulations subject to the FCC's jurisdiction, and/or international treaties (collectively referred to hereafter as FCC Rules and Regulations);
2. Maintaining documents and tracking the status of formal complaints,

including, but not limited to those that involve market disputes;

3. Determining the levels of compliance among FCC licensees and other regulatees;

4. Documenting the Commission's monitoring, overseeing, auditing, inspecting, and investigating for compliance and enforcement purposes;

5. Providing a basis for the various administrative and civil or criminal actions against violators by EB, other appropriate Commission bureaus or offices, and/or other government agencies;

6. Gathering background information for reference materials from various external sources that include, but are not limited to, databases, documents, files, and other related resources, to ensure that the information that is being compiled is accurate and up-to-date (cross-checking) in the course of investigating consumer complaints and/or enforcement investigations;

7. Maintaining archival information (paper documents and files) for reference in enforcement investigations and other actions; and

8. Preventing duplication of FCC's enforcement actions, *e.g.*, for cross-reference purposes, etc.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records in this system include, but are not limited to:

1. Individuals, including FCC employees, who have filed complaints alleging violations of FCC Rules and Regulations; or individuals who have filed such complaints on behalf of other entities and who may have included their personally identifiable information (PII) in the complaint;

2. Individuals who are or have been the subjects of FCC enforcement actions, including field monitoring, inspection, and investigation, for possible violations of FCC Rules and Regulations;

3. Licensees, applicants, regulatees, and unlicensed individuals about whom there are questions of compliance with FCC Rules and Regulations; and

4. FCC employees, contractors, and interns who perform work on behalf of EB.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in this system include, but are not limited to:

1. Information that is associated with those individuals who file complaints or who are being investigated for possible enforcement actions. The information may include:

(a) An individual's name, Social Security Number (SSN) or Taxpayer Identification Number (TIN), gender,

race/ethnicity, birth date/age, place of birth, biometric data (photograph(s)), marital status, spousal data, miscellaneous family data, home address, home address history, home telephone number(s), personal cell phone number(s), personal fax number(s), personal email address(es), personal criminal background report(s), credit card number(s), driver license number(s), bank account data, financial data, law enforcement data, background investigatory data, national security data, employment and/or employer data, and other miscellaneous materials, documents, files, and records used for background information, data verification, and other purposes.

(b) Inspection reports, audit reports, complaints, referrals, monitoring reports, inspection cases, referral memos, correspondence, audio and sound recordings, photographs, discrepancy notifications, warning notices, forfeiture actions, and other related materials.

(c) Miscellaneous materials, documents, files, and records that are used for background information and data verification concerning individuals who may have been alleged to or have violated the Commission's Rules and Regulations.

2. Information that is associated with the same or similar current enforcement investigations and historic records and other archival, background, and research data and materials that are stored for reference in enforcement actions, including inspection reports, complaints, monitoring reports, investigative cases, referral memos, correspondence, discrepancy notifications, warning notices, and forfeiture actions; and

3. Other, miscellaneous information that complainants may have included on informal consumer complaint forms, interference reports, as well as any additional FCC forms and complaint data intake systems that may be used from time to time to report possible violations of FCC Rules and Regulations to the FCC or associated with case files.

RECORD SOURCE CATEGORIES:

Sources of records include individuals submitting complaints, relevant law enforcement databases, publicly available electronic information and data, and individuals who have been contacted during investigations to be sources of information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C.

552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside the FCC as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows.

1. Public Access—Names and other information about individuals subject to investigations or similar actions may be disclosed to the public in Commission releases, including Notices of Apparent Liability, Forfeiture Orders, Consent Agreements, Notice Letters, or all other actions released by EB or the Commission as part of their duties to enforce FCC Rules and Regulations.

2. Due Diligence Inquiries—Where there is an indication of a violation or potential violation of FCC Rules and Regulations, records from this system may be shared with a requesting individual, or representative thereof, for purposes of obtaining such information so long as the information is relevant to a pending transaction of an FCC-issued license.

3. FCC Enforcement Actions—When a record in this system involves an informal complaint filed alleging a violation of FCC Rules and Regulations by an applicant, licensee, certified or regulated entity, or an unlicensed person or entity, the complaint may be provided to the alleged violator for a response. Where a complainant in filing his or her complaint explicitly requests confidentiality of his or her name from public disclosure, the Commission will endeavor to protect such information from public disclosure. Complaints that contain requests for confidentiality may be dismissed if the Commission determines that the request impedes the Commission's ability to investigate and/or resolve the complaint.

4. Litigation—To disclose records to the Department of Justice (DOJ) when: (a) the FCC or any component thereof; (b) any employee of the FCC in his or her official capacity; (c) any employee of the FCC in his or her individual capacity where the DOJ or the FCC has agreed to represent the employee; or (d) the United States Government is a party to litigation or has an interest in such litigation, and by careful review, the FCC determines that the records are both relevant and necessary to the litigation, and the use of such records by the Department of Justice is for a purpose that is compatible with the purpose for which the FCC collected the records.

5. Adjudication—To disclose records in a proceeding before a court or adjudicative body, when: (a) the FCC or any component thereof; or (b) any

employee of the FCC in his or her official capacity; or (c) any employee of the FCC in his or her individual capacity; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the FCC determines that the records are both relevant and necessary to the litigation, and that the use of such records is for a purpose that is compatible with the purpose for which the agency collected the records.

6. Law Enforcement and Investigation—When the FCC investigates any violation or potential violation of a civil or criminal law, regulation, policy, executed consent decree, order, or any other type of compulsory obligation, to disclose pertinent information as it deems necessary to the target of an investigation, as well as with the appropriate Federal, State, local, Tribal agency, or a component of such an agency, responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order.

7. Congressional Inquiries—To provide information to a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the written request of that individual.

8. Government-wide Program Management and Oversight—To the Department of Justice (DOJ) to obtain that department's advice regarding disclosure obligations under the Freedom of Information Act (FOIA); or the Office of Management and Budget (OMB) to obtain that office's advice regarding obligations under the Privacy Act.

9. Breach Notification—To appropriate agencies, entities, and persons when: (a) the Commission suspects or has confirmed that there has been a breach of the system of records; (b) the Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

10. Assistance to Federal Agencies and Entities Related to Breaches—To another Federal agency or Federal entity, when the Commission determines that information from this system is reasonably necessary to assist the recipient agency or entity in: (a) responding to a suspected or confirmed

breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

11. Non-Federal Personnel—To disclose information to non-Federal personnel, including contractors, other vendors (*e.g.*, identity verification services), grantees, and volunteers who have been engaged to assist the FCC in the performance of a service, grant, cooperative agreement, or other activity related to this system of records and who need to have access to the records in order to perform their activity.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Information in this information system consists of:

1. Electronic records, files, and data are stored in the FCC's computer network databases, at headquarters; and
2. Paper records, documents, and files are stored in filing cabinets in the EB office suites at headquarters and in field offices (on an *ad hoc*, temporary basis when needed to resolve enforcement cases in their jurisdictions as needed for limited periods).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

1. Information in the electronic database information can be retrieved by the name(s) of the individual(s) who filed the complaint(s), the individual who is subject of the complaint, and by a unique file number assigned to each type of activity conducted by the Bureau, *e.g.*, internal initiative investigations, complaint investigations, cases, market dispute mediations, formal adjudications, hearings, due diligence requests, etc.

2. Information in the central files, which includes, but is not limited to, paper documents, records, and files, includes all the other information pertaining to these internal initiative investigations, complainant investigations, and/or cases. This information may include, but is not limited to, name, address, and telephone number, and is maintained for reference and archival purposes. This information is retrieved by a unique identification file number assigned to each internal initiative investigation, complainant investigation, and/or case.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The information in this electronic system is maintained and disposed of in

accordance with the National Archives and Records Administration (NARA) General Records Schedule No. DAA–0173–2014–0002–0002.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The electronic records, data, and files are maintained in the FCC computer network databases at headquarters, which are protected by the FCC's IT privacy safeguards, a comprehensive and dynamic set of IT safety and security protocols and features that are designed to meet all Federal IT privacy standards, including those required by the National Institute of Standard and Technology (NIST) and the Federal Information Security Modernization Act of 2014 (FISMA). The paper documents and files are maintained in file cabinets in "non-public" rooms in the EB office suite at headquarters and in field offices. The file cabinets are locked at the end of the business day. Access to the EB offices at both headquarters and field offices is via a key and card-coded door.

Authorized EB supervisors and staff have access to the information in both the electronic files databases and paper document files, and IT contractors, who maintain these electronic files databases, also have access to them. Other FCC employees, interns, and contractors may be granted access to the information in the electronic and paper formats only on a "need-to-know" basis.

RECORD ACCESS PROCEDURES:

Under the authority granted to heads of agencies by 5 U.S.C. 552a(k), the FCC has determined that this system of records is exempt from providing record access procedures for this system of records, 47 CFR 0.561.

CONTESTING RECORD PROCEDURES:

Under the authority granted to heads of agencies by 5 U.S.C. 552a(k), the FCC has determined that this system of records is exempt from providing contesting record procedures for this system of records, 47 CFR 0.561.

NOTIFICATION PROCEDURES:

Under the authority granted to heads of agencies by 5 U.S.C. 552a(k), the FCC has determined that this system of records is exempt from providing notification procedures for this system of records, 47 CFR 0.561.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

This system of records is exempt from sections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) of the Privacy Act of 1974, and from 47 CFR 0.554–0.557 of the Commission's rules. These provisions concern the notification,

record access, and contesting procedures described above, and also the publication of record sources. The system is exempt from these provisions because it contains investigative material compiled for law enforcement purposes as defined in Section (k) of the Privacy Act.

HISTORY:

(75 FR 77872) (December 14, 2010).

Federal Communications Commission.

Marlene Dortch,
Secretary.

[FR Doc. 2023–13973 Filed 6–29–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Tuesday, July 11, 2023 at 10:30 a.m. and its continuation at the conclusion of the open meeting on July 13, 2023.

PLACE: 1050 First Street NE, Washington, DC and Virtual.
(This meeting will be a hybrid meeting.)

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Vicktoria J. Allen,

Deputy Secretary of the Commission.

[FR Doc. 2023–14041 Filed 6–28–23; 11:15 am]

BILLING CODE 6715–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0199; Docket No. 2023–0053; Sequence No. 5]

Information Collection; Prohibition on Contracting With Entities Using Certain Telecommunications and Video Surveillance Services or Equipment

AGENCY: Department of Defense (DOD), General Services Administration (GSA),

and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on a revision concerning Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment. DoD, GSA, and NASA invite comments on: whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through November 30, 2023. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by August 29, 2023.

ADDRESSES: DoD, GSA, and NASA invite interested persons to submit comments on this collection through <https://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov.

Instructions: All items submitted must cite OMB Control No. 9000-0199, Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment. Comments received generally will be posted without change to <https://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Malissa Jones, Procurement Analyst, at

telephone 571-882-4687, or malissa.jones@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and any Associated Form(s)

9000-0199, Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment.

B. Need and Uses

DoD, GSA, and NASA are combining OMB Control Nos. for the Federal Acquisition Regulation (FAR) by FAR part. This consolidation is expected to improve industry's ability to easily and efficiently identify burdens associated with a given FAR part. The review of the information collections by FAR part allows improved oversight to ensure there is no redundant or unaccounted for burden placed on industry. Lastly, combining information collections in a given FAR part is also expected to reduce the administrative burden associated with processing multiple information collections.

This justification supports the revision of OMB Control No. 9000-0199 and combines it with the previously approved information collections under OMB Control No(s). 9000-0201, with the title "Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment". Upon approval of this consolidated information collection, OMB Control No(s). 9000-0201 will be discontinued. The burden requirements previously approved under the discontinued number(s) will be covered under OMB Control No. 9000-0199.

This clearance covers the information that offerors and contractors must submit to comply with the following FAR requirements listed in the order in which offerors and contractors provide the information:

- *FAR 52.204-26, Covered Telecommunications Equipment or Services—Representation.* This provision requires offerors to:

- Review the list of excluded parties in SAM for entities excluded from receiving Federal awards for "covered telecommunications equipment or services".

- Represent whether it does or does not *provide* covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

- Represents whether it does, or does not *use* covered telecommunications

equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services.

- *FAR 52.204-24, Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.* This provision requires offerors to respond only if the offeror represented that it "does *provide* or *use* covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument" in paragraphs (c)(1) or (c)(2) of the FAR provision at 52.204-26, or in paragraphs (v)(2)(i) or (ii) of the provision at 52.212-3.

If the offeror is required to respond to this provision, offerors are required to:

- Review the list of excluded parties in SAM for entities excluded from receiving Federal awards for "covered telecommunications equipment or services,"

- Represent whether it "will" or "will not" *provide* the covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from the solicitation.

- If the offeror responded that it "will" in the representation in paragraph (d)(1) of this provision, the offeror must provide the following additional disclosure information found at 52.204-24(e)(1) as part of its offer:

- For covered equipment—

- The entity that produced the covered telecommunications equipment (including entity name, unique entity identifier, Commercial and Government Entity (CAGE) code, and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known);

- A description of all covered telecommunications equipment offered (including brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

- An explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of the provision at 52.204-24.

- For covered services—

- If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part

number, or wholesaler number; and item description, as applicable); or

- If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and an explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of the provision at 52.204–24.

- Represent whether it “does” or “does not” use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services.

- If the offeror has responded “does” in the representation in paragraph (d)(2) of this provision, the offeror must provide the following additional disclosure information found at 52.204–24(e)(2):

- For covered equipment—
 - The entity that produced the covered telecommunications equipment (including entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known);

- A description of all covered telecommunications equipment offered (including brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

- An explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of the provision at 52.204–24.

- For covered services—

- If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

- If not associated with maintenance, the PSC of the service being provided; and an explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of the provision at 52.204–24.

- *FAR 52.204–25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.* In the event a contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or

as critical technology as part of any system, during contract performance, or a contractor is notified of such by a subcontractor at any tier or by any other source, this clause requires contractors to:

- Report the information in paragraph 52.204–25(d)(2) to the contracting officer, unless the contract has established other procedures for reporting the information; in the case of DoD, the contractor shall report to the website at <https://dibnet.dod.mil>.

- For indefinite delivery contracts, the contractor shall report to the contracting officer for the indefinite delivery contract and the contracting officer(s) for any affected order or, in the case of DoD, identify both the indefinite delivery contract and any affected orders in the report provided at <https://dibnet.dod.mil>.

- Report the following within one business day from the date of such identification or notification:

- The contract number;
- The order number(s), if applicable;
- Supplier name;
- Supplier unique entity identifier (if known);
- Supplier CAGE code (if known);
- Brand;
- Model number (original equipment manufacturer number, manufacturer part number, or wholesaler number);
- Item description;
- And any readily available information about mitigation actions undertaken or recommended.

- Report the following within 10 business days of submitting the information in paragraph(d)(2)(i) of this clause:

- Any further available information about mitigation actions undertaken or recommended.
- Describe efforts undertaken to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

The information collected is used by contracting officers to identify if an offeror *provides* or *uses* any covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument. In the event that offerors are required to disclose further information, the contracting officer uses the collected information to ensure compliance with the FAR as implemented by statute and consult with legal counsel and the program office on next steps regarding the prohibited equipment or services.

C. Annual Burden

Respondents: 902,777.

Total Annual Responses: 905,213.

Total Burden Hours: 1,839,573.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000–0199, Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment.

William Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2023–13916 Filed 6–29–23; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Revisions to Recordkeeping To Mitigate the Spread of COVID–19 in Head Start (OMB #: 0970–0583)

AGENCY: Office of Head Start; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, requests public comment on an extension with changes to recordkeeping requirements for ACF Head Start grant recipients. A Final Rule published on January 6, 2023, added a recordkeeping requirement that Head Start grant recipients update their program policies and procedures to include an evidence-based COVID–19 mitigation policy. OHS requested and received emergency approval from OMB to implement the updated recordkeeping requirement as required in the Final Rule. Approval was for 6 months. Subsequently, a final rule was published on June 26, 2023, which removed all previously approved vaccination recordkeeping requirements and the requirement to maintain a testing protocol. This request is to remove these requirements from the information collection and extend approval of the remaining recordkeeping requirement under this OMB number for an additional 3 years.

DATES: Comments due within 30 days of publication. OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The final rule on January 6, 2023, added a requirement that Head

Start grant recipients update their program policies and procedures to include an evidence-based COVID-19 mitigation policy developed in consultation with their Health Services Advisory Committee. This is the only remaining recordkeeping requirement in this information collection. Vaccination and testing protocol recordkeeping requirements and associated burdens have been removed.

Respondents: Recipients of Head Start funding.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Responses per respondent	Average burden hours per response	Annual burden hours
Grant Recipient Updating Program Policies and Procedures	160	1	2	320

Authority: 45 CFR part 1302.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–13893 Filed 6–29–23; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Multistate Financial Institution Data Match With Federally Assisted State Transmitted Levy

AGENCY: Office of Child Support Services, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of an information collection; request for public comments.

SUMMARY: The Office of Child Support Services (OCSS), Administration for Children and Families (ACF), is requesting the federal Office of Management and Budget (OMB) to extend approval of the Multistate Financial Institution (MSFIDM) Data Match with Federally Assisted State Transmitted (FAST) Levy, without changes, for an additional three years. The current OMB approval (OMB No.: 0970–0169) expires January 31, 2024.

DATES: Comments due within 60 days of publication. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: State child support agencies are statutorily required to enter into data matching agreements with financial institutions doing business in their state to locate obligors' accounts. OCSS operates the MSFIDM program through the Federal Parent Locator Service (FPLS) and facilitates the required data match between state child support agencies and multistate financial institutions (MSFIs). State child support agencies use the data match outcomes to fulfill a statutory requirement to seize an obligor's assets to satisfy past-due child support.

OCSS also operates FAST Levy, which is an automated application within the FPLS to exchange electronic lien/levy information securely and efficiently. State child support agencies and financial institutions use FAST Levy to exchange information to freeze and seize financial assets more quickly and efficiently.

Respondents: MSFIs and State Child Support Agencies

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total annual number of respondents	Total annual number of responses per respondent	Average annual burden hours per response	Total annual burden hours
Financial Data Match Record Specifications Match File Upload/Download: Portal Users	263	4	0.083	87.3
Election Form	13	1	0.5	6.5
FAST-Levy Response Withhold Record Specifications: Financial Institutions	1	1	1,716	1,716.0
FAST-Levy Request Withhold Record Specifications: State Child Support Agencies	2	1	1,610	3,220.0

Estimated Total Annual Burden Hours: 5,029.8.

Comments: The Department specifically requests comments on (a)

whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the

information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility,

and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 652(l); 42 U.S.C. 666(a)(2) and (c)(1)(G)(ii); 42 U.S.C. 666(a)(17)(A); 42 U.S.C. 652(a)(7); and, 45 CFR 303.7(a)(5)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023-13885 Filed 6-29-23; 8:45 am]

BILLING CODE 4184-41-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; SHIP-SMP Survey of Group Outreach and Education Events (OMB Control Number 0985-0056)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the Proposed Revision and solicits comments on the information collection requirements related to the “National SHIP-SMP Beneficiary Survey of Group Outreach and Education Events.”

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by July 31, 2023.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT:

Shefy Simon, Administration for Community Living, Washington, DC 20201, 202-795-7572, shefy.simon@acl.hhs.gov.

SUPPLEMENTARY INFORMATION:

In compliance with the Paperwork Reduction Act, ACL has submitted the following proposed information collection to OMB for review and clearance. The SHIP-SMP Survey of Group Outreach and Education Events is a survey of individuals who attend outreach and education events provided by the State Health Insurance Assistance Program (SHIP) or Senior Medicare Patrol (SMP). These events help Medicare beneficiaries understand their Medicare benefits and options. These events also increase the ability of beneficiaries to identify fraud, waste, and abuse within health care programs generally, and Medicare/Medicaid specifically. The State Health Insurance Assistance Program (SHIP) was created under the Omnibus Budget Reconciliation Act of 1990.

This section of the law authorized the Department of Health and Human Services (HHS) to make grants to states to establish and maintain health insurance advisory service programs for Medicare beneficiaries. Grant funds were made available to support information, counseling, and assistance activities related to Medicare, Medicaid, and other health insurance options.

The Senior Medicare Patrol (SMP) program was authorized in 1997 under Titles II and IV of the Older Americans Act, the Omnibus Consolidated Appropriation Act of 1997 and the Health Insurance Portability and Accountability Act of 1996. The SMP mission is to empower and assist Medicare beneficiaries, their families, and caregivers, to prevent, detect, and report suspected healthcare fraud, errors, and abuse through outreach, counseling, and education. SMP grantees support ACL's goals of promoting increased choice and greater independence among older adults and individuals with disabilities. SMP activities enhance the financial, emotional, physical, and mental well-being of older adults, thereby increasing their capacity to maintain security in retirement and make better financial and healthcare choices. SHIP-SMP grantees provide group outreach and education through presentation events, and this collection will survey the attendees of those events.

The SHIP-SMP Survey of Group Outreach and Education Events will focus on group outreach and education events and the individuals who attend

them, to determine if the target audience is satisfied with the information they are receiving. This is an extension with change to the Senior Medicare Program National Beneficiary Survey.

The Office of Healthcare Information and Counseling (OHIC) conducted an evaluation of the Medicare Improvements for Patients and Providers Act (MIPPA) in 2022–23 that invoked the need to include collecting demographic data, including sexual orientation and gender identity (SOGI) information, in all the work OHIC touches and not just MIPPA grant work. ACL is adding the collection of SOGI data to this extension of the SHIP-SMP Survey of Group Outreach and Education Events. Including sexual orientation and gender identity questions in this information collection will provide data on topics such as the accessibility and utilization of services and programs funded by ACL by lesbian, gay, bisexual, and transgender populations and the health disparities that impact this community. Understanding these disparities can and should lead to improved service delivery for ACL's programs and populations served.

An important gap in sociodemographic information on the SHIP-SMP Survey of Group Outreach and Education Events is a lack of items collecting sexual orientation and gender identity. Adding sexual orientation and gender identity items to SHIP-SMP Survey of Group Outreach and Education Events is part of ACL's strategy to address “Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation.” Issued in January 2021, Executive Order 13988 called upon agencies to identify existing and new policies to promote equal treatment under the law and ensure that all persons are able to access healthcare and other essential services without being subjected to sex discrimination.

To support alignment with Executive Order 13988, as well as Executive Orders 13985 and 14075, three items will be added to SHIP-SMP Survey of Group Outreach and Education Events to collect sexual orientation and gender identity. The first item will ask the individual if they think of themselves as gay/lesbian, straight, bisexual, or something else.

This item has been fielded on the NHIS since 2013, where it has been closely monitored for comprehension and sensitivity. The second and third items are part of a two-step series to collect gender identity, which requires two items to accurately collect. Respondents are first asked to report

their sex assigned at birth on their original birth certificate (male, female, don't know, prefer not to answer). Next, respondents are asked to report their current gender identity (male, female, transgender, I use a different term, prefer not to answer). This two-step

series aligns with recommendations from the National Academies of Sciences, Engineering, and Medicine's (NASEM's) recent report, "Measuring Sex, Gender Identity, and Sexual Orientation." These items have also been cognitively tested for inclusion in

the Medicare Current Beneficiaries Survey under the MCBS Generic Clearance and performed well.

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents (maximum)	Responses per respondent	Hours per response	Annual burden hours
Survey, Stratified Random Sample	5,400	1	5/60	450
Total	5,400	1	5/60	450

Dated: June 19, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023-13968 Filed 6-29-23; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2286]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary National Retail Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with our Voluntary National Retail Food Regulatory Program (VNRFRP) Standards.

DATES: Either electronic or written comments on the collection of information must be submitted by August 29, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of August 29, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-2286 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary National Retail Food Regulatory Program Standards." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.regulations.gov>

www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Voluntary National Retail Food Regulatory Program Standards

OMB Control Number 0910-0621—Revision

This information collection helps support implementation of FDA's Voluntary National Retail Food Regulatory Program Standards (the Retail Program Standards). Regulatory Program Standards play a critical role in an integrated food safety system and serve as the foundation for mutual reliance between FDA and other regulatory agencies that work to ensure food safety. The Retail Program Standards define what constitutes a highly effective and responsive program for the regulation of foodservice and retail food establishments. The Retail Program Standards are intended to provide a foundation upon which continuous improvements can be made with the ultimate goal to reduce the occurrence of factors that cause and contribute to foodborne illness. In support of this goal, FDA works cooperatively with our State, local, Territorial, and Tribal partners using a risk-based approach to leverage limited resources. We engage in education and outreach efforts to facilitate collaboration with our partners in food safety. The Retail Program Standards represent an important component of a comprehensive strategic approach to help ensure the safety and security of the food supply at the retail level. Respondents to the information collection are State, local, territorial, and tribal governments.

The Retail Program Standards were revised most recently in August 2022 and include the following elements: (1) regulatory foundation; (2) trained regulatory staff; (3) inspection program based on Hazard Analysis and Critical Control Point (HACCP) principles; (4) uniform inspection program; (5) foodborne illness and food defense preparedness and response; (6) compliance and enforcement; (7) industry and community relations; (8) program support and resources; and (9) program assessment. These elements are enumerated and discussed on our website at [https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-august-](https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-august-2022)

2022 along with worksheets and assessments that allow FDA to determine conformance with the Retail Program Standards. State, local, territorial, tribal, and Federal regulatory agencies that participate in the voluntary program are required to report information demonstrating that a program self-assessment, a risk factor study of the regulated industry, and an independent outside audit (verification audit) have been completed. The information also includes Form FDA 3958, "Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report," which may be completed electronically at [https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards-august-2022](https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-august-2022).

Finally, we are revising the information collection to include additional Agency resources. We have created a dedicated mailbox at retailfoodprotectionteam@fda.hhs.gov to receive requests for program documentation and have developed the following instruments to support the standardization of food safety inspection officer candidates:

- Proposed Form FDA 5017, "Standardized Retail Food Safety Inspection Officer Waiver of Annual Maintenance Requirement Form," pertains to requests for waivers from maintenance requirements, referenced in section 3-403 of the "FDA Procedures for Standardization of Retail Food Safety Inspection Officers." FDA uses the information submitted on Form FDA 5017 to determine a food safety inspection officer's eligibility for re-standardization.

- Proposed Form FDA 5018, "Standardized Retail Food Safety Inspection Officer Annual Maintenance Form," provides verification that a food safety inspection officer has met program standardization requirements in accordance with section 3-403 of the "FDA Procedures for Standardization of Retail Food Safety Inspection Officers."

- Proposed Form FDA 5019, "Standardized Food Safety Inspection Officer Nomination Form," allows FDA to collect qualification information from food safety inspection officer candidates.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Voluntary National Retail Program Standards (August 2022)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Program self-assessments for element Nos. 1 through 8.	500	1	500	92.3	46,150
Program element No. 9; risk factor study and intervention strategy.	500	1	500	333	166,500
Program Verification audit	500	1	500	46.15	23,075
Program records; associated documentation/maintenance of worksheets, assessments, associated program tools.	500	1	500	94.29	47,145
FDA Form 3958; VNRFP National Registry Report	500	1	500	0.1 (6 minutes)	50
Requests for program documentation (dedicated email).	500	3	1,500	0.1 (6 minutes)	150
Proposed Form FDA 5017; Waiver of Annual Maintenance Requirement.	10	1	10	0.35 (21 minutes) ..	3.5
Proposed Form FDA 5018; Food Safety Inspection Officer Annual Maintenance.	130	1	130	0.35 (21 minutes) ..	43
Proposed Form FDA 5019; Food Safety Inspection Officer Nomination.	14	1	14	0.35 (21 minutes) ...	5
.....			4,154		283,121.5

¹ There are no capital or operational and maintenance costs associated with this collection of information.

Our estimate of burden for the associated program activities as identified in table 1 is based on our experience with the information collection, along with other regulatory standards programs we administer. Upon reorganizing the collection to reflect the cumulative activities, we have accounted for burden that may be attributable recordkeeping for risk-factor studies and verification tasks that may have been previously overlooked. The burden we attribute to completing and submitting FDA Form 3958, “Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report,” is exclusive of other program records, which we account for in row 4. We have also accounted for burden we assume will be attendant to the completion and submission of newly developed Agency forms. As a result of these changes and adjustments, the information collection reflects an increase of 235,776.5 hours and 1,654 responses annually.

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13930 Filed 6–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–1427; FDA–2022–N–0863; FDA–2023–N–0187; FDA–2013–N–1393; FDA–2022–D–0814; FDA–2013–N–0796; FDA–2016–N–0736; and FDA–2019–N–3065]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have

been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice	0910–0466	4/30/2026
Monthly Monitoring Study	0910–0914	4/30/2026
Premarket Approval of Medical Devices	0910–0231	5/31/2026
Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions	0910–0233	5/31/2026
Infant Formula Requirements	0910–0256	5/31/2026
Testing Communications on Medical Devices and Radiation-Emitting Products	0910–0678	5/31/2026
Tracking Network for PETNet, LivestockNet, and SampleNet	0910–0680	5/31/2026
Required Warnings for Cigarette Packages and Advertisements	0910–0877	5/31/2026

Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13936 Filed 6–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1096]

Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the development of drugs or biological products for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP). Specifically, this guidance addresses FDA’s current thinking regarding trial population and design, effectiveness, statistical analysis, and safety for drugs being developed for the treatment of CRSwNP. This guidance finalizes the draft guidance of the same title issued on December 10, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on June 30, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2021–D–1096 for “Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Rekha Jhamnani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3395, Silver Spring, MD 20993–0002, 301–796–5636; or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.” The guidance provides recommendations for sponsors developing products for the treatment of CRSwNP. Specifically, this guidance represents FDA’s current thinking regarding trial population and design, effectiveness, statistical analysis, and safety for drugs being developed for the treatment of CRSwNP. This guidance does not address the clinical development of drugs for the treatment

of chronic rhinosinusitis without nasal polyps or allergic fungal rhinosinusitis.

This guidance finalizes the draft guidance of the same title issued on December 10, 2021 (86 FR 70505). FDA considered comments received on the draft guidance in this finalized guidance. Chronic rhinosinusitis is characterized by inflammation of the nasal mucosa and paranasal sinuses and can be further divided into chronic rhinosinusitis with and without nasal polyps. Nasal polyps are inflammatory hyperplastic growths that protrude into the nasal passages. Symptoms of CRSwNP include nasal congestion, nasal discharge, facial pain or pressure, and loss of smell. Nasal polyps have associated morbidity that can have substantial impact on day-to-day functioning. Because of differences in natural history and treatment between chronic rhinosinusitis with and without nasal polyps, this guidance specifically addresses aspects of trial design, safety and efficacy assessment for CRSwNP. Changes from the draft to the final guidance include considerations for efficacy assessments for CRSwNP.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of

information contained in 21 CFR part 312 relating to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to new drug applications have been approved under OMB control number 0910–0001. The collections of information contained in 21 CFR part 601 relating to biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13884 Filed 6–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0438]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 29, 2023.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 264–0041 and PRA@HHS.GOV.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, PRA@HHS.GOV or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: FY2020 Teen Pregnancy Prevention (TPP) Program Performance Measures.

Type of Collection: Extension.

OMB No.: 0990–0438.

Abstract: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), requests a renewal clearance for the collection of performance measures specifically for FY2020 Teen Pregnancy Prevention (TPP) Program grantees. Collection of performance measures is a requirement of all TPP awards and is included in the NOFOs. The data collection will allow OPA to comply with federal accountability and performance requirements, inform stakeholders of grantee progress in meeting TPP program goals, provide OPA with metrics for monitoring TPP grantees, and facilitate individual grantees' continuous quality improvement efforts within their projects. OPA requests clearance for one year to cover reporting during the no-cost extension period of the awards.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Grantees (partners and sustainability)	All TPP grantees	90	2	15/60	45
Grantees (training)	All TPP Grantees	90	2	15/60	45
Grantees (dissemination)	All TPP Grantees	90	2	30/60	90
Grantees (Stakeholder Engagement)	All TPP Grantees	90	2	15/60	45
Grantees (Reach and Demographics)	Tier 1 and Tier 2 Phase II Grantees ..	64	2	3	384
Grantees (Dosage)	Tier 1 and Tier 2 Phase II Grantees ..	64	2	2	256
Grantees (Fidelity and Quality)	Tier 1 and Tier 2 Phase II Grantees ..	64	2	2	256

ANNUALIZED BURDEN HOUR TABLE—Continued

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Total			2		1,155

Sherrette A. Funn,

*Paperwork Reduction Act Reports Clearance
Officer, Office of the Secretary.*

[FR Doc. 2023–13909 Filed 6–29–23; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information: Draft HHS 2023 Framework To Support and Accelerate Smoking Cessation

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice of request for information.

SUMMARY: The Department of Health and Human Services (HHS or Department) is issuing this request for information (RFI) to receive input from the public on the Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation to guide the Department's efforts to sustain and strengthen existing programs and drive further progress toward smoking cessation, with an emphasis on serving populations and communities disproportionately impacted by smoking-related morbidity and mortality.

DATES: To be assured consideration, comments must be received at the email address provided below, no later than midnight Eastern Time (ET) on July 30, 2023. HHS will not reply individually to responders but will consider all comments submitted by the deadline. Please do not provide confidential information as comments may be published or otherwise used for agency purposes.

ADDRESSES: Please submit all comments via email to HHSSmokingCessationFramework2023@hhs.gov as a Word document, Portable Document Format (PDF), or in the body of an email. Please include "Request for Information: Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation" in the subject line of the email message.

FOR FURTHER INFORMATION CONTACT: Please submit questions for further information to Sarah Boateng, Principal Deputy Assistant Secretary for Health.

Email: sarah.boateng@hhs.gov at (202) 205–0725.

SUPPLEMENTARY INFORMATION: The mission of HHS is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

On February 22, 2022, President Joe Biden and First Lady Jill Biden reignited the Cancer Moonshot, setting an ambitious, achievable goal: to reduce the death rate from cancer by at least 50 percent over the next 25 years and improve the experience of people and families living with and surviving cancer, ultimately ending cancer as we know it. Additionally, on January 20, 2021, President Biden signed Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, which directed the Department to make achieving health equity part of its mission by developing programs, policies, and activities to address the disproportionately high and adverse health disparities in underserved communities. Then on February 16, 2023, President Biden signed Executive Order 14091, *Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. This second Executive Order reaffirmed the Administration's commitment to health equity by extending and strengthening equity-advancing requirements for agencies.

To support the executive order initiatives, and to pursue the Administration's priorities for advancing health equity and driving down cancer deaths, the Office of the Assistant Secretary for Health (OASH) is leading the development of a framework to support and accelerate smoking cessation. The Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation (the Framework) will provide direction to enhance collaboration and coordination across HHS, and with Federal and non-Federal stakeholders, drive further progress toward smoking cessation and delivering equitable outcomes for all persons in America. The draft Framework was developed with valued

input from subject matter experts across HHS Operating Divisions. The Framework aims to accelerate smoking cessation and reduce smoking-related health disparities by building on current activities and collaborations across the Department, including work guided by the HHS Tobacco Control Strategic Action Plan developed in 2010.

The scope is focused on cessation of the use of commercial cigarettes, cigars, and cigarillos, for people of all ages across the lifespan. The Department also recognizes the importance of tobacco use prevention and cessation of other tobacco products. These issues as well as those related to e-cigarettes are topics that are out of scope for this phase but will be addressed in a later phase of this effort.

The purpose of this request for information (RFI) is to seek public comment on the Draft 2023 Framework to Support and Accelerate Smoking Cessation. Please see the Draft Framework below, followed by an RFI in the form of questions to the public.

Draft U.S. Department of Health and Human Services 2023 Framework To Support and Accelerate Smoking Cessation

Background

Cigarette smoking is the leading cause of preventable disease, disability, and death in the United States, including about 30% of all cancer deaths. Enormous progress has been made over the last 60 years in driving down rates of cigarette smoking. In 2021, 11.5% of U.S. adults smoked cigarettes, down from an all-time high of 42%, and two-thirds (66.5%) of all adults who ever smoked cigarettes have quit. Despite this progress, cigarette smoking still claims approximately 480,000 American lives every year.

Furthermore, the gains that have been made over the past several decades have not occurred equally across the population, leaving behind many of those who have the least resources and who face the greatest barriers to quitting. Encouraging and assisting every person in America to quit smoking is critical to ensuring a healthier future for all people in America and to helping achieve the Cancer Moonshot goal of reducing cancer death rates by at least half over

the next 25 years, a central part of President Biden's Unity Agenda, issues areas where all of us can come together and make additional progress for the American people. In fact, ahead of the President's State of the Union, the Administration announced that helping Americans avoid smoking in the first place and supporting Americans who want to quit would be a major priority for the President's Cancer Moonshot this year.

Vision

The Framework vision is to ensure that every person in America has access to comprehensive, evidence-based cessation treatment and can benefit from HHS cessation supports, programs, and policies.

Framework Goals

The Framework is organized around the six goals that serve as a foundation for long-standing HHS efforts to support and promote cessation. Moving forward, these goals will guide future HHS cessation actions, building on the work that is already underway to achieve the Framework vision.

The Framework identifies six goals.

1. Eliminate smoking- and cessation-related disparities
2. Increase awareness and knowledge related to smoking and cessation
3. Strengthen and sustain cessation services and supports
4. Increase access to and coverage of comprehensive, evidence-based cessation treatment
5. Expand surveillance of smoking and cessation behaviors and strengthen performance measurement and evaluation
6. Promote ongoing and innovative research to support and accelerate smoking cessation

Cross-Cutting Principles

The Framework is underpinned by cross-cutting guiding principles that apply across all six goals. These cross-cutting principles reflect the Department's commitment to leveraging the best available smoking cessation science, programs, and policies to reach diverse populations and all communities across America.

- *Advancing Equity:* Employ culturally competent strategies that support and accelerate cessation, focusing especially on groups with high smoking prevalence and/or persistent cessation-related disparities
- *Community Engagement:* Ensure that the public, especially communities that are disproportionately affected by smoking, are engaged in the development and implementation of

cessation programs, policies, and infrastructure

- *Coordination, Collaboration, and Integration:* Promote coordination, collaboration, and integration of programs and activities across HHS to support the implementation and sustainability of effective cessation practices, programs, and policies
- *Evidence-Based Approaches:* Leverage the strongest evidence base to guide actions for cessation treatment and messaging, while identifying research gaps and needs

Broad Strategies

Each of the six goals are supported by broad strategies to drive progress toward smoking cessation at the population and individual levels. HHS will advance the Framework goals through coordinated strategies that leverage the full capacity and resources of the Department, including continued support for ongoing activities that serve these goals.

Goal 1: Eliminate Smoking- and Cessation-Related Disparities

Addressing disparities in smoking prevalence rates and cessation outcomes is essential to achieving equitable progress in reducing smoking-related morbidity and mortality. A commitment to health equity involves understanding health disparities related to smoking and the factors that cause these disparities. Through the Framework, HHS seeks to execute broad strategies that will reach all communities and address unique barriers to cessation experienced by disparately affected groups.

Examples of broad strategies that advance this goal include:

- Promoting access to cessation resources that are culturally competent and use consumers' preferred languages
- Engaging community partners in promotion and outreach to key population groups, focusing especially on groups with high smoking prevalence and/or persistent cessation-related disparities
- Building capacity for cessation services and supports in care settings serving key populations
- Regulating the manufacturing, marketing, and distribution of tobacco products to protect public health

Goal 2: Increase Awareness and Knowledge Related to Smoking and Cessation

Raising knowledge and awareness about the harmful effects of smoking and evidence-based cessation interventions drives attempts to quit and promotes treatment utilization.

Through the Framework, HHS seeks to execute broad strategies that will increase awareness and knowledge related to smoking and cessation.

Examples of broad strategies that advance this goal include:

- Expanding public education campaigns to increase knowledge about the harms of smoking and the availability of cessation services
- Coordinating with Federal and non-Federal entities to share cessation communication and education resources in order to amplify their reach
- Promoting covered cessation treatments to insurance beneficiaries and their health care providers

Goal 3: Strengthen and Sustain Cessation Services and Supports

To help people quit smoking, it is important to have strong cessation supports in place with sustainable capacity and infrastructure. Through the Framework, HHS seeks to execute broad strategies that will support implementation of services that are evidence-based, optimally effective, engaging, and sustainable.

Examples of broad strategies that advance this goal include:

- Strengthening and sustaining State and local cessation programs and activities
- Working to ensure a baseline level of service for State tobacco Quitlines
- Promoting connectivity and interoperability among HHS programs and partnerships with other Federal and non-Federal entities

Goal 4: Increase Access to and Coverage of Comprehensive High-Quality Cessation Treatment

Ensuring that high-quality, comprehensive cessation support is accessible and affordable for all people in America is essential for advancing smoking cessation. The Framework seeks to execute broad strategies that will increase access to cessation treatment, especially in settings serving population groups that experience barriers to cessation and cessation-related disparities.

Examples of broad strategies that advance this goal include:

- Working with health insurers, payers, States, health care facilities, community providers, and other stakeholders to remove coverage barriers to treatment
- Ensuring that smoking assessment and treatment delivery and referral are integrated into healthcare systems and connected to care for other health conditions

- Supporting, reimbursing, and evaluating innovative healthcare delivery methods that support cessation and provide long-term support to prevent and address relapse
- Promoting patient-centered approaches and ensuring that cessation protocols are evidence-based

Goal 5: Expand Surveillance of Smoking and Cessation Behaviors and Strengthen Performance Measurement and Evaluation

Expanding capacity for surveillance and evaluation is critical for measuring progress, understanding barriers to quitting success, and rewarding effective service delivery. Through the Framework, HHS seeks to execute strategies that will support the measurement, monitoring, and tracking of patterns, trends, and progress.

Examples of broad strategies that advance this goal include:

- Ensuring that surveillance systems can capture cessation-related disparities and diverse tobacco use patterns
- Promoting development and use of common data elements
- Supporting program evaluation to ensure that high quality smoking cessation and related services are provided

Goal 6: Promote Ongoing and Innovative Research To Support and Accelerate Smoking Cessation

A robust evidence base exists to inform smoking cessation programs, policies, and treatments. At the same time, it is essential to identify what gaps exist in our current understanding of what works to effectively address smoking cessation. Through the Framework, HHS seeks to execute broad strategies that will support research efforts to continually build the evidence base in this area.

Examples of broad strategies that advance this goal include:

- Increasing understanding of how to optimize current smoking cessation interventions to maximize reach and treatment engagement and effectiveness, particularly among populations disparately impacted by smoking
- Supporting research on new cessation interventions
- Promoting sharing of data and resources generated by federally-funded research
- Identifying research gaps

HHS is requesting information from the public regarding five questions.

1. Are the proposed goals appropriate and relevant for addressing the needs of populations disparately affected by smoking?

2. Do the broad strategies capture the key components and aspects needed to drive progress toward increasing cessation?

3. Are there additional goals or broad strategies that should be included in the Framework?

4. What targeted actions should HHS (Department-wide or within a specific HHS agency) take to advance these goals and strategies?

5. What metrics and benchmarks should be included to ensure that the Framework drives progress?

HHS invites all potentially interested parties—individuals, associations, governmental and non-governmental organizations, academic institutions, and private sector entities—to respond. HHS is interested in the questions listed above, but respondents are welcome to address as many or as few as they choose and may provide additional relevant information that is within the scope of the Framework. To facilitate review of the responses, please reference the question number in your response.

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of HHS to provide support for any ideas in response to it. HHS will use the information submitted in response to this RFI at its discretion and will not provide comments to any respondent's submission. However, responses to this RFI may be reflected in future initiatives, solicitations, or policies. Respondents are advised that HHS is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted.

Sarah N. Boateng,

Principal Deputy Assistant Secretary for Health, Office of the Assistant Secretary for Health.

[FR Doc. 2023-13928 Filed 6-29-23; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Listing of Members of the Indian Health Service Senior Executive Service Performance Review Board

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is provided of the persons who will serve on the Indian Health Service Senior Executive Service Performance Review Board.

SUPPLEMENTARY INFORMATION: The Indian Health Service (IHS) announces the persons who will serve on the IHS Senior Executive Service Performance Review Board (PRB). This action is being taken in accordance with 5 U.S.C. 4314(c)(4), which requires that members of PRBs be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals; and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons may be named to serve on the PRB from 2023–2025, which oversees the evaluation of performance appraisals and compensation for Senior Executive Service, Senior Level/Senior Technical, and Title 42 executive-equivalent members of the IHS.

Buchanan, Chris
Cooper, Jennifer
Cotton, Beverly
Curtis, Jillian
Driving Hawk, James
Frye, Daniel
Gaikowski, Dixie
Gyorda, Lisa
LaRoche, Darrell
Redgrave, Bryce
Smith, Phillip B. (Chair)
Watts, Travis

For further information about the PRB, contact Nathan Anderson, Office of Human Resources, Indian Health Service, 5600 Fishers Lane, Rockville, MD 20857, or by phone at 605–681–4940.

P. Benjamin Smith,

Deputy Director, Indian Health Service.

[FR Doc. 2023-13892 Filed 6-29-23; 8:45 am]

BILLING CODE 4165-16-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 meeting.

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: July 20, 2023.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435-1743, margaret.chandler@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Molecular Bacterial Pathogenesis.

Date: July 25, 2023.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joshua David Powell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-5370, josh.powell@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Biology: AREA/REAP.

Date: July 26, 2023.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301-402-4788, sarita.sastry@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: June 26, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-13905 Filed 6-29-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity PAR Review.

Date: July 17, 2023.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, barnardm@extra.niddk.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 26, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-13904 Filed 6-29-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Learning, Memory and Decision Neuroscience.

Date: July 12, 2023.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Roger Janz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-8515, janzr2@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, 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: June 26, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-13907 Filed 6-29-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurobiology of Motivated Behavior, Neurotoxicology, and Alcohol.

Date: July 31, 2023.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Eileen Marie Moore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-8928, eileen.moore@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: June 27, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-13923 Filed 6-29-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Development of Medications to Prevent and

Treat Opioid and/or Stimulant Use Disorders and Overdose.

Date: August 2, 2023.

Time: 12:30 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sudhirkumar Udhavrao Yanpallewar, M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, Bethesda, MD 20892, (301) 443-4577, sudhirkumar.yanpallewar@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: June 26, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-13906 Filed 6-29-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Rescission of Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended

AGENCY: Office of the Secretary, (DHS).

ACTION: Notice of rescission of determination.

SUMMARY: On May 15, 2020, the Acting Secretary of Homeland Security published a Notice of Determination Pursuant to Section 102 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended, to waive legal requirements related to the construction of barriers and roads. (May 2020 Notice of Determination). The Secretary of Homeland Security through this notice rescinds the May 2020 Notice of Determination.

DATES: This Notice takes effect on June 30, 2023.

SUPPLEMENTARY INFORMATION: Section 102(c) of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, as Amended, provides the Secretary of Homeland Security with the sole discretion to waive all legal requirements related to the construction of barriers and roads. Public Law 104-208, Div. C, 110 Stat. 3009-546, 3009-

554 (Sept. 30, 1996) (8 U.S.C 1103 note), as amended by the REAL ID Act of 2005, Public Law 109-13, Div. B, 119 Stat. 231, 302, 306 (May 11, 2005) (8 U.S.C. 1103 note), as amended by the Secure Fence Act of 2006, Public Law 109-367, section 3, 120 Stat. 2638 (Oct. 26, 2006) (8 U.S.C. 1103 note), as amended by the Department of Homeland Security Appropriations Act, 2008, Public Law 110-161, Div. E, Title V, section 564, 121 Stat. 2090 (Dec. 26, 2007). Any such waivers shall be effective upon being published in the **Federal Register**. On May 15, 2020, the Acting Secretary of Homeland Security issued a **Federal Register** notice determining that it was “necessary to waive certain laws, regulations, and other legal requirements in order to ensure the expeditious construction of barriers and roads in the vicinity of the international land border in Webb County, Texas, and Zapata County, Texas.” See 85 FR 29472. Through this Notice, the Secretary of Homeland Security hereby rescinds the May 15, 2020 Notice of Determination.

This rescission of the May 15, 2020 Notice of Determination does not rescind or supersede any other waiver determination made pursuant to section 102(c) of IIRIRA. Such waivers shall remain in full force and effect in accordance with their terms.

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2023-13924 Filed 6-29-23; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA-CISA-2023-0003]

Agency Information Collection Activities: .gov Registrar

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; new collection (request for a new OMB control number).

SUMMARY: The .gov Registry Program within the Cybersecurity and Infrastructure Security Agency (CISA) will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. CISA previously published this information collection request (ICR) in the **Federal Register** on February 27,

2023 for a 60-day public comment period. 0 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 July 31, 2023. This process is conducted in accordance with 5 CFR 1320.10.

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: Cameron Dixon, DHS, Cybersecurity and Infrastructure Security Agency/ Cybersecurity Division, 888–282–0870, dotgov@cisa.dhs.gov.

SUPPLEMENTARY INFORMATION: *.gov* is a ‘top-level domain’ (TLD), similar to *.com*, *.org*, or *.us*. Enterprises use a TLD to register a “domain name” (often simply called a domain) for use in their online services, like a website or email. Well-known *.gov* domains include *whitehouse.gov*, *congress.gov*, or *uscourts.gov*, but most *.gov* domains are from non-federal governments like *ny.gov* (State of New York) or *lacounty.gov* (LA County).

.gov is only available to bona fide U.S.-based government organizations and publicly controlled entities. When governments use *.gov*, they make it harder for would-be impostors to successfully impersonate them online.

Under the DOTGOV Act of 2020 (6 U.S.C. 665), CISA is responsible for the operation and security of the *.gov* TLD. Pursuant to that law, the *.gov* program at CISA works to “provide simple and secure registration of *.gov* internet domains”, “ensure that domains are registered and maintained only by authorized individuals”, and “minimize the risk of *.gov* internet domains whose names could mislead or confuse users”. In order to provision *.gov* domains to eligible government entities and ensure adherence to the domain requirements published by CISA pursuant to 6 U.S.C. 665(c), CISA needs to collect information from requestors of *.gov* domains.

The information will be collected on an online web portal called the “*.gov* registrar”, which is built and maintained by CISA. Requestors will be asked to provide information on the characteristics of their government entity (e.g., name, type, physical location, current domain), their preferred *.gov* domain name (e.g., *example.gov*), their rationale for the name, organizational contact information (names, phone numbers, email addresses), and nameserver addresses.

Only U.S.-based government organizations are eligible for *.gov* domains; some of these organizations may be small entities. The collection has been developed to request only the information needed to confirm eligibility and adjudicate a *.gov* domain request. Without this collection, CISA will be unable to assess the eligibility of requestors nor provision *.gov* domains to government organizations. That outcome would decrease cybersecurity for governments across the nation and minimize the public’s ability to identify governments online.

In accordance with 6 U.S.C. 665(c)(4), CISA will “limit the sharing or use of any information” obtained through this collection “with any other Department component or any other agency for any purpose other than the administration of the *.gov* internet domain, the services described in subsection (e), and the requirements for establishing a *.gov* inventory described in subsection (h).” Certain metadata for any approved domains (domain name, organization name, nameserver address, city/state information, security contact) will be published online.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: *.gov* registrar.

OMB Number: OMB CONTROL NUMBER.

Frequency: Once per domain registered.

Affected Public: Employees representing State, local, Territorial, and Tribal governments.

Number of Respondents: 1500 per year.

Estimated Time per Respondent: 20 minutes.

Total Burden Hours: 500 hours.

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintaining): \$24,674.

Robert J. Costello,

Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2023–13831 Filed 6–29–23; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–NWRS–2023–0098; FXRS1263090000/FF09R81000/234; OMB Control Number 1018–0181]

Agency Information Collection Activities; U.S. Fish and Wildlife Service Concessions

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection without change.

DATES: Interested persons are invited to submit comments on or before August 29, 2023.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (reference “1018–0181” in the subject line of your comment):

- *Internet (preferred):* <https://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS–HQ–NWRS–2023–0098.

- *Email:* Info_Coll@fws.gov.

- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection

Clearance Officer, by email at *InfoColl@fws.gov*, or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Secretary of the Interior is authorized to ensure that we provide opportunities within the Service for compatible wildlife-dependent recreational uses across the National Wildlife Refuge System (System). Furthermore, the Secretary is authorized to award concessions contracts under the following Acts:

- The National Wildlife Refuge System Administration Act of 1966 (Administration Act, 16 U.S.C. 668dd–668ee), as amended by the National Wildlife Refuge System Improvement Act of 1997, authorizes the Secretary of the Interior to negotiate and award contracts and issue regulations to carry out the Administration Act.
- The Refuge Recreation Act of 1962 (16 U.S.C. 460k–460k–3) allows the use of refuges for public recreation when such use is not inconsistent with or does not interfere with the primary purpose(s) of the refuge.
- The Refuge Revenue Sharing Act (16 U.S.C. 715s) authorizes the Secretary to grant privileges and collect revenues from leases for public accommodations or facilities established for the System.

Specifically, the Administration Act provides that, with respect to the Refuge System, it is the policy of the United States that—

- a. Each refuge shall be managed to fulfill the mission of the System, as well as the specific purposes for which that refuge was established;
- b. Compatible wildlife-dependent recreation is a legitimate and appropriate general public use of the System, directly related to the mission of the System and the purposes of many refuges, and which generally fosters refuge management and through which the American public can develop an appreciation for fish and wildlife;
- c. Compatible wildlife-dependent recreational uses are the priority general public uses of the System and shall receive priority consideration in refuge planning and management; and
- d. When the Secretary determines that a proposed wildlife-dependent recreational use is a compatible use within a refuge, that activity should be facilitated, subject to such restrictions or regulations as may be necessary, reasonable, and appropriate.

The Administration Act also provides that, in administering the Refuge System, the Secretary shall—

- a. Recognize compatible wildlife-dependent recreational uses as the priority general public uses of the System, through which the American

public can develop an appreciation for fish and wildlife;

- b. Ensure that opportunities are provided within the System for compatible wildlife-dependent recreational uses;

- c. Ensure that priority general public uses of the System receive enhanced consideration over other general public uses in planning and management within the System; and

- d. Provide increased opportunities for families to experience compatible wildlife-dependent recreation, particularly opportunities for parents and their children to safely engage in traditional outdoor activities, such as fishing and hunting.

Private businesses and non-profit organizations under contract to the Service provide recreational, educational, and interpretive enjoyment of our lands and waters by managing lodging, food, transportation, and supplies and equipment for the enjoyment of the visiting public. These services gross approximately \$3,000,000 every year and provide jobs for more than 100 people annually.

The regulations at 50 CFR subpart F (section 25.61) primarily implement the authorities governing public use facilities operated by concessionaires or cooperators under appropriate contact or legal agreement on national wildlife refuges where there is a demonstrated justified need for services or facilities, including but not limited to boat rentals, swimming facilities, conducted tours of special natural attractions, shelters, tables, trailer lots, food, lodging, and related services.

Service Manual chapters 630 FW 6–8 discuss the Service's current policy for concession management and provide guidance for permitting and administering concessions operations on Service lands. We use concessions contracts to assist us in providing wildlife-dependent recreation activities to the visiting public by using contracts between the Service and private entities, where each private entity is allowed to charge a fee for services provided at a field station to the visiting public.

We collect information in a narrative (non-form) format. Details concerning the specific information required are contained in 50 CFR 25.61 and the recently updated Service Manual chapters available to the public on the Service's website at <https://www.fws.gov/policy/manuals/part.cfm?series=600&seriestitle=LAND%20USE%20AND%20MANAGEMENT%20SERIES>. The amount of information or degree of detail requested varies widely, depending upon the size and scope of the business opportunity. For

example, a much greater amount of detailed information would be required for a multi-unit camping and food service operation than would be required for a small bait sales operation. We use the information provided by prospective concessionaires to objectively evaluate offers received for a particular business opportunity, assure adequate protection of refuge resources, and to determine which offeror will provide the best service to visitors.

Below are examples of types of information the Service collects from a potential or current concessionaire.

General Concessionaire Information

- Description of how the respondent will conduct operations to minimize disturbance to wildlife; protect refuge resources; and provide visitors with a high-quality, safe, and enjoyable visitor experience.
- Proposal to protect, conserve, and preserve resources of the refuge. The proposal must respond to specific resource management objectives and issues at the refuge and regarding the contract in question.
- Proposal to provide necessary and appropriate visitor services at reasonable rates. This proposal must respond to specific visitor service questions at the refuge and regarding the contract in question.
- Experience and related background of the offeror, including past performance and expertise of the offeror in providing the same or similar visitor services as those to be provided under the draft concession contract.

- Financial capability of the offeror to carry out its proposal. In particular, we require projected financials, including initial investments, startup expenses, income statement, operating assumptions, cash flow statement, recapture of investments, and all associated assumptions.

- The amount of the proposed minimum franchise fee and other forms of financial consideration.

Proposal for Concession Opportunity

- Offeror's transmittal letter, including the name and contact information of the entity offering a proposal to operate a concession contract.
- Business type of the offeror, such as corporation, limited liability company, partnership, etc.
- Business history information, including adverse history that could impact future operations under a concession contract.
- Credit report, so that we can understand the offeror's credit history and any risks of contracting with the entity.
- Proposed staffing/management operation information, including organization charts and delegations of authority, to ensure adequate staffing.
- Proof of indemnification, including public liability insurance that co-names the Government as co-insured.

Reporting Requirements

- Annual financial reports providing concessioner financial information, as required by each concession contract.
- Quarterly and annual progress reports to monitor performance.

- Inspections and inspection reports conducted in concert with the on-site concession manager.

Approval to Sell or Transfer Concession Operation

- Information to assess the transferee's ability to manage the business successfully and fulfill the terms of the concession contract, in order for the Regional Director to grant approval.

Recordkeeping Requirements

- In accordance with Service Manual chapter 630 FW 8.3, a concessioner (and any subconcessioner) must keep and make available to the Service records for the term of the concession contract.

Title of Collection: U.S. Fish and Wildlife Service Concessions.

OMB Control Number: 1018–0181.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Private sector (profit and nonprofit organizations).

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

Frequency of Collection: On occasion for proposals, amendments, and appeals; annually for financial reports; quarterly for progress reports; and ongoing for recordkeeping.

Total Estimated Annual Nonhour Burden Cost: \$69,900 (associated with administrative overhead, as well as costs associated with the development of proposals in response to concessions opportunities).

Requirement	Average number of annual respondents	Average number of responses each	Average number of annual responses	Average completion time per response (hours)	Estimated annual burden hours *
Approval to Sell/Transfer A Concession Operation	1	1	1	8	8
General Concessionaire Information—Inspection Form	80	1	80	8	640
Proposal for Concessions Opportunities—Large Concessions	3	2	6	40	240
Proposal for Concessions Opportunities—Small Concessions	3	1	3	16	48
Recordkeeping Requirements—Large Concession	5	1	5	40	200
Recordkeeping Requirements—Small Concession	5	1	5	20	100
Reporting Requirements—Annual Financial Report	10	1	10	16	160
Reporting Requirements—Annual Progress Report	10	1	10	16	160
Reporting Requirements—Quarterly Progress Report	3	4	12	4	48
Totals	120		132		1,604

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2023–13959 Filed 6–29–23; 8:45 am]

BILLING CODE 4333–15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R7–MB–2023–N053; FF07M01000–234–FXMB12310700000; OMB Control Number 1018–0168]

Agency Information Collection Activities; Submission to the Office of Management and Budget; Northeast Region Alaska Native Handicrafts

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act, we, the U.S. Fish and Wildlife Service, are proposing to renew an information collection without change.

DATES: Interested persons are invited to submit comments on or before July 31, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to Info_Coll@fws.gov. Please reference “1018–0168” in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access

telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA; 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

On March 20, 2023, we published in the **Federal Register** (88 FR 16660) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on May 19, 2023. In an effort to increase public awareness of, and participation in, our public commenting processes associated with information collection requests, the Service also published the **Federal Register** notice on [Regulations.gov](https://www.regulations.gov) (Docket No. FWS–R7–MB–2023–0001) to provide the public with an additional method to submit comments (in addition to the typical *Info_Coll@fws.gov* email and U.S. mail submission methods). We received two comments in response to that notice; however, they did not address the information collection requirements. No response to those comments is required.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public’s reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of

information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Migratory Bird Treaty Act of 1918 (16 U.S.C. 712(1)) authorizes the Secretary of the Interior, in accordance with the treaties with Canada, Mexico, Japan, and Russia, to “issue such regulations as may be necessary to assure that the taking of migratory birds and the collection of their eggs, by the indigenous inhabitants of the State of Alaska, shall be permitted for their own nutritional and other essential needs, as determined by the Secretary of the Interior, during the Alaska spring and summer migratory bird subsistence harvest seasons so as to provide for the preservation and maintenance of stocks of migratory birds.” Article II(4)(b) of the Protocol between the United States and Canada amending the 1916 Convention for the Protection of Migratory Birds in Canada and the United States (Protocol) provides a legal basis for Alaska Native people to be able to sell handicrafts that contain the inedible parts of birds taken for food during the Alaska spring and summer migratory bird subsistence harvest. The Protocol also dictates that sales would be allowed in strictly limited situations, pursuant to a regulation by a competent authority in cooperation with management bodies. The Protocol does not authorize the taking of migratory birds for commercial purposes.

In 2017, we issued a final rule (July 24, 2017, 82 FR 34263), developed under a co-management process involving the Alaska Department of Fish and Game and Alaska Native representatives, that amended the permanent migratory bird subsistence harvest regulations at 50 CFR 92.6 to enable Alaska Native people to sell authentic native articles of handicraft or

clothing that contain inedible byproducts from migratory birds that were taken for food during the Alaska migratory bird subsistence harvest season. Article II(4)(b) of the Protocol dictates that sales will be under strictly limited situations. The sale by Alaska Native people of a limited number of handicrafts containing inedible migratory bird parts provides a small source of additional income that we conclude is necessary for the “essential needs” of Alaska Native people in predominantly rural Alaska. This limited opportunity for sale is consistent with the language of the Protocol and is expressly noted in the Letter of Submittal dated May 20, 1996, for the Treaty Protocol, specifically Article II(4)(b) of the Protocol, to be consistent with the customary and traditional uses of Alaska Native people. The activity by Alaska Native people is also consistent with the preservation and maintenance of migratory bird stocks.

Alaska Native artists will show eligibility with a Tribal enrollment card, Bureau of Indian Affairs card, or membership in the Silver Hand program. The State of Alaska Silver Hand program helps Alaska Native artists promote their work in the marketplace and enables consumers to identify and purchase authentic Alaska Native art. The Silver Hand insignia indicates that the artwork on which it appears is created by hand in Alaska by an individual Alaska Native artist. Only original contemporary and traditional Alaska Native artwork, not reproductions or manufactured work, may be identified and marketed with the Silver Hand insignia. To be eligible for a 2-year Silver Hand permit, an Alaska Native artist must be a full-time resident of Alaska, be at least 18 years old, and provide documentation of membership in a federally recognized Alaska Native tribe. The Silver Hand insignia may only be attached to original work that is produced in the State of Alaska.

The final rule requires that FWS Form 3–2484 (a simple certification which is not subject to the PRA) or a Silver Hand insignia accompany each Alaska Native article of handicraft or clothing that contains inedible migratory bird parts. It also requires all consignees, sellers, and purchasers to retain this documentation with each item and produce it upon the request of a law enforcement officer. The final rule also requires that artists maintain adequate records of the certification or Silver Hand insignia with each item and requires artists and sellers/consignees to provide the documentation to buyers. These

recordkeeping and third-party notification requirements are subject to the PRA and require OMB approval.

The public may request copies of a Form 3–2484 contained in this information collection by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**).

Title of Collection: Alaska Native Handicrafts, 50 CFR 92.6.

OMB Control Number: 1018–0168.

Form Numbers: 3–2484.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals and businesses.

Total Estimated Number of Annual Respondents: 2 (placeholder of 1 respondent associated with the regulatory requirement for each respondent category).

Total Estimated Number of Annual Responses: 2.

Estimated Completion Time per Response: 5 minutes.

Total Estimated Number of Annual Burden Hours: 0.

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

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2023–13960 Filed 6–29–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[234A2100DD/AAKC001030/AOA501010.999900]

Indian Gaming; Extension of Tribal-State Class III Gaming Compact (Middletown Rancheria of Pomo Indians of California & State of California)

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces the extension of the Class III gaming compact between the Middletown Rancheria of Pomo Indians of California & State of California.

DATES: The extension takes effect on June 30, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: An extension to an existing Tribal-State Class III gaming compact does not require approval by the Secretary if the extension does not modify any other terms of the compact. 25 CFR 293.5. The Middletown Rancheria of Pomo Indians of California and the State of California have reached an agreement to extend the expiration date of their existing Tribal-State Class III gaming compact to December 31st, 2024. This publication provides notice of the new expiration date of the compact.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2023–14084 Filed 6–29–23; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM 2023–0037]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Beacon Wind Project on the U.S. Outer Continental Shelf Offshore Massachusetts

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of intent (NOI) to prepare an environmental impact statement (EIS); request for comments.

SUMMARY: Consistent with the regulations implementing the National Environmental Policy Act (NEPA), BOEM announces its intent to prepare an EIS for a construction and operations plan (COP) submitted by Beacon Wind LLC (Beacon Wind). This NOI initiates the public scoping and comment process under NEPA and also seeks public comments under section 106 of the National Historic Preservation Act (NHPA) and its implementing regulations. Beacon Wind proposes to construct and operate an offshore wind facility located in Renewable Energy Lease Area OCS–A 0520 (Lease Area), which is approximately 128,811 acres and 17 nautical miles (nm) south of Nantucket, Massachusetts, and 52 nm east of Montauk, New York. Beacon Wind, a joint venture owned by Equinor U.S. Holdings, Inc. and BP Wind Energy North America, Inc., proposes to develop the entire Lease Area in two

wind farms, known as Beacon Wind 1 (BW1) and Beacon Wind 2 (BW2) (collectively, the Project).

DATES: Your comments must be received by BOEM on or before July 31, 2023 for timely consideration.

Public Participation:

BOEM will hold two in-person and two virtual public scoping meetings for the Beacon Wind EIS at the following dates and times (eastern time):

In Person:

- Tuesday, July 18, 2023, 6:00–9:00 p.m., UMASS-Dartmouth, The Market Place Dining Hall, 285 Old Westport Road, Dartmouth, MA 02747; and

- Thursday, July 20, 2023, 6:00–9:00 p.m., Adria Hotel and Conference Center Ballroom, 221–17 Northern Blvd., Queens, NY 11361–3600

Virtual:

- Thursday, July 13, 2023, 11:00 a.m.–1:00 p.m.; and

- Wednesday, July 26, 2023, 11:00 a.m.–1:00 p.m.

Registration for the virtual public meetings may be completed here: <https://www.boem.gov/renewable-energy/state-activities/beacon-wind> or by calling (888) 788 0099 (toll free). Registration for in-person meetings will occur on site. The meetings are open to the public and free to attend.

ADDRESSES: Written comments can be submitted in any of the following ways:

- Delivered by mail or delivery service, enclosed in an envelope labeled “BEACON WIND EIS” and addressed to Jessica Stromberg, Chief, Environmental Branch for Renewable Energy, Bureau of Ocean Energy Management, 45600 Woodland Road, VAM-OREP, Sterling, Virginia 20166; or

- *Through the regulations.gov web portal:* Navigate to www.regulations.gov and search for Docket No. BOEM–2023–0037. Select the document in the search results on which you want to comment, click on the “Comment” button, and follow the online instructions for submitting your comment. A commenter’s checklist is available on the comment web page. Enter your information and comment, then click “Submit.”

Detailed information about the proposed Project, including the COP and instructions for making written comments, can be found on BOEM’s website at: www.boem.gov/renewable-energy/state-activities/beacon-wind.

FOR FURTHER INFORMATION CONTACT: Bonnie Houghton, Office of Renewable Energy Programs, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166, telephone (703) 438–5108, or email Bonnie.Houghton@boem.gov.

SUPPLEMENTARY INFORMATION:

Purpose of and Need for the Proposed Action

In Executive Order 14008, “Tackling the Climate Crisis at Home and Abroad,” issued on January 27, 2021, President Biden stated that the policy of his administration is “to organize and deploy the full capacity of its agencies to combat the climate crisis to implement a Government-wide approach that reduces climate pollution in every sector of the economy; increases resilience to the impacts of climate change; protects public health; conserves our lands, waters, and biodiversity; delivers environmental justice; and spurs well-paying union jobs and economic growth, especially through innovation, commercialization, and deployment of clean energy technologies and infrastructure.”

Through a competitive leasing process conducted under 30 CFR 585.211, BOEM awarded Equinor Wind US, LLC, the commercial wind energy lease OCS–A 0520. Beacon Wind acquired 100 percent interest in the Lease Area by assignment effective January 27, 2021, and, has the exclusive right to submit a COP for activities in it.

Beacon Wind submitted a COP to BOEM proposing the construction, operation, maintenance, and conceptual decommissioning of two offshore wind energy facilities (BW1 & BW2) in Lease Area OCS–A–0520. Beacon Wind’s goal is to develop two offshore wind energy facilities in the Lease Area to provide renewable energy to the State of New York and other northeastern States. Beacon Wind proposes to construct up to 155 wind turbine generators (WTG) with 2 offshore substations (OSS), for a total of up to 157 structures in a 1 nm x 1 nm grid distributed across the Lease Area (Proposed Action). The individual wind farms within the Lease Area would be electrically isolated and independent from one another. Transmission systems would connect each OSS to separate onshore points of interconnection (POIs).

BW1 has a 25-year offtake agreement with the New York State Energy Research and Development Authority (NYSERDA) and is expected to deliver 1,230 megawatts (MW) of power to the NYISO electric grid at a POI in Queens, New York. Beacon Wind is actively seeking an offtake agreement for BW2 in the New England and New York region. Beacon Wind anticipates that BW2 will deliver more than 1,200 MW of power and interconnect with either the NYISO grid in Queens or with the New England Independent System Operator (ISO–NE) grid in Waterford, Connecticut.

BW1 would supply electricity in support of renewable and offshore wind energy goals established by the State of New York under its 2019 Climate Leadership and Community Protection Act. Among other things, the law mandates that at least 70 percent of New York’s electricity come from renewable energy sources by 2030 and that 9,000 MW come from offshore wind energy by 2035. If BW2 also obtains an offtake agreement with NYSERDA, it would supply additional electricity along the same cable route as BW1 in support of New York’s goals.

Based on BOEM’s authority under the Outer Continental Shelf Lands Act (OCSLA) (43 U.S.C. 1331 *et seq.*) to authorize renewable energy activities on the Outer Continental Shelf and its obligations under the lease, BOEM’s purpose is to determine whether to approve, approve with modifications, or disapprove Beacon Wind’s COP. BOEM’s purpose supports the policies stated in Executive Order 14008 and the Federal goal to deploy 30 gigawatts of offshore wind energy capacity in the United States by 2030, while protecting biodiversity and promoting ocean co-use. BOEM will make its determination after weighing the EIS analysis and the enumerated goals in subsection 8(p)(4) of OCSLA.

In addition, the National Oceanic and Atmospheric Administration’s National Marine Fisheries Service (NMFS) anticipates one or more requests for authorization under the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*) to take marine mammals incidental to Project activities. NMFS’s decision whether to issue an incidental take authorization is a major Federal action connected to BOEM’s action (40 CFR 1501.9(e)(1)). The purpose of the NMFS action—which is a direct outcome of Beacon Wind’s request for authorization to take marine mammals incidental to Project activities (e.g., pile driving)—is to evaluate Beacon Wind’s request under the MMPA and its implementing regulations, which are administered by NMFS. NMFS will consider the impacts of Beacon Wind’s activities on relevant resources and, if appropriate, issue the permit or authorization. NMFS must render a decision regarding Beacon Wind’s request for incidental take authorization under the MMPA (16 U.S.C. 1371(a)(5)(D)), its implementing regulations, and NMFS’s delegated authorities. If NMFS decides to authorize incidental takes, NMFS intends to adopt, after independent review, BOEM’s EIS to support that decision and fulfill its NEPA requirements.

The U.S. Army Corps of Engineers (USACE) New England District anticipates permit applications from Beacon Wind for actions undertaken through authority delegated to the district engineer under section 10 of the Rivers and Harbors Act of 1899 (RHA) (33 U.S.C. 403) and section 404 of the Clean Water Act (CWA) (33 U.S.C. 1344). In addition, Beacon Wind may need section 408 permission pursuant to 33 U.S.C. 408, for any actions it proposes to take that have the potential to alter, occupy, or use any existing federally authorized projects. USACE considers issuance of permits and permissions under these three delegated authorities a major Federal action connected to BOEM's action (40 CFR 1501.9(e)(1)).

As determined by USACE for section 404(b)(1) guidelines evaluation, the basic Project purpose is offshore wind energy generation. Beacon Wind's need, as provided in the COP and reviewed by USACE for NEPA purposes, is to generate electricity from offshore wind energy facilities located in Lease Area OCS-A 0520.

As determined by Engineer Circular 1165-2-220, the purpose of USACE section 408 action is to evaluate Beacon Wind's request and determine whether its Proposed Action would adversely impact the public interest or a USACE project. USACE section 408 permission is needed to ensure that congressionally authorized projects continue to provide their intended benefits to the public. USACE intends to adopt BOEM's EIS in accordance with 40 CFR 1506.3 if, after its independent review of the document, USACE concludes that BOEM has satisfactorily addressed its comments and recommendations. USACE intends to adopt BOEM's EIS to support its decision on any permits or permissions requested under sections 10 and 14 of the RHA and section 404 of the CWA. Based on its participation as a cooperating agency and its consideration of BOEM's EIS, USACE intends to issue a record of decision (ROD) to formally document its decision on the Proposed Action.

Proposed Action and Preliminary Alternatives

Beacon Wind proposes to construct and operate two offshore wind energy facilities within Lease Area OCS-A-0520, with up to 157 total foundation locations to be occupied by a combination of up to 155 WTGs and 2 OSSs. Offshore components for BW1 and BW2 include between 61 and 94 WTGs and 1 OSS each, foundations and associated scour protection for WTGs, associated inter-array cables, 1 high-

voltage direct current (HVDC) submarine export cable route each, cable protection, and 1 temporary meteorological and oceanographic (metocean) buoy. Beacon Wind is considering monopile, piled jacket, or suction-bucket jacket foundation types to support the WTG. The OSS would be supported by either piled jacket or suction-bucket jacket foundations. The WTGs, OSSs, foundations, and inter-array cables would be located entirely within the Lease Area. The submarine export cables would be buried in the U.S. Outer Continental Shelf and in the seabed under the State waters of New York and potentially of Connecticut (if the export cable from BW2 makes landfall in Waterford, Connecticut).

The BW1 submarine export cable would make landfall and interconnect to the NYISO grid in Queens. The BW2 cable would make landfall in either Queens or Waterford; if landfall is in Waterford, the cables would interconnect with the ISO-NE grid in Connecticut. BW1's onshore components would be sited in Queens, and BW2's in either Queens or Waterford.

BOEM will evaluate reasonable alternatives to the Proposed Action that are identified during the scoping period and included in the draft EIS, including a no action alternative. Under the no action alternative, BOEM would disapprove the Beacon Wind COP, and the proposed wind energy facilities described in the COP would not be built within the Lease Area.

After completing the EIS and associated consultations, BOEM will decide through a ROD whether to approve, approve with modification, or disapprove the Beacon Wind COP. If BOEM approves the COP, Beacon Wind must comply with all conditions of its approval.

Summary of Potential Impacts

The draft EIS will identify and describe the potential effects of the Proposed Action and the alternatives on the human environment. Those potential effects must be reasonably foreseeable and must have a reasonably close causal relationship to the Proposed Action and the alternatives. Such effects include those that occur at the same time and place as the Proposed Action and alternatives and those that are later in time or occur in a different place. Potential effects include, but are not limited to, impacts (whether beneficial or adverse) on air quality, water quality, bats, benthic habitat, essential fish habitat, invertebrates, finfish, birds, marine mammals, terrestrial and coastal habitats and

fauna, sea turtles, wetlands and other waters of the United States, commercial fisheries and for-hire recreational fishing, cultural resources, Tribal issues of concern, demographics, employment, economics, environmental justice, land use and coastal infrastructure, navigation and vessel traffic, other marine uses, recreation and tourism, and visual resources. These potential effects will be analyzed in the draft and final EIS.

Based on a preliminary evaluation of the resources listed in the preceding paragraph, BOEM expects potential impacts on sea turtles and marine mammals from underwater noise caused by construction and from collision risks with Project-related vessel traffic. Structures installed by the Project could permanently change benthic and fish habitats (*e.g.*, creation of artificial reefs). Commercial fisheries and for-hire recreational fishing could be impacted. Project structures above the water could affect the visual character defining historic properties and recreational and tourism areas. Project structures also would pose an allision and height hazard to vessels passing close by, and vessels would, in turn, pose a hazard to the structures. Additionally, the Project could cause conflicts with military activities, air traffic, land-based radar services, cables and pipelines, and scientific surveys. The EIS will analyze all impacts, as well as potential measures that would avoid, minimize, or mitigate identified non-beneficial impacts.

Beneficial impacts are also expected by facilitating achievement of State renewable energy goals, increasing job opportunities, improving air quality, and addressing climate change through E.O. 14008. The Project is estimated to support 5,958 to 6,491 job-years cumulatively during the development and construction phases, including indirect and induced employment opportunities. During the operations and maintenance phase, the Project is estimated to support 21,117 to 22,681 jobs-years during an estimated 40 years of operation and maintenance (including decommissioning).

Anticipated Permits and Authorizations

In addition to the requested COP approval, various other Federal, State, and local authorizations will be required for the Project. Applicable Federal laws include the Endangered Species Act, Magnuson-Stevens Fishery Conservation and Management Act, MMPA, RHA, CWA, Clean Air Act section 328, and the Coastal Zone Management Act. BOEM will also conduct government-to-government

Tribal consultations. For a detailed listing of regulatory requirements applicable to the Project, please see the COP, volume I, available at www.boem.gov/renewable-energy/state-activities/beacon-wind.

BOEM has chosen to use the NEPA process to fulfill its obligations under NHPA. While BOEM's obligations under NHPA and NEPA are independent, regulations implementing section 106 of NHPA allow the NEPA process and documentation to substitute for various aspects of the NHPA review. See 36 CFR 800.8(c). This process is intended to improve efficiency, promote transparency and accountability, and support a broadened discussion of potential effects that the Project could have on the human environment. During preparation of the EIS, BOEM will ensure that the NEPA process will fully meet all NHPA obligations.

Schedule for the Decision-Making Process

After the draft EIS is completed, BOEM will publish a notice of availability (NOA) and request public comments on the draft EIS. BOEM currently expects to issue the NOA in July 2024. After the public comment period ends, BOEM will review and respond to comments received and will develop the final EIS. BOEM currently expects to make the final EIS available to the public in March 2025. A ROD will be completed no sooner than 30 days after the final EIS is released, in accordance with 40 CFR 1506.11.

This Project is a "covered project" under section 41 of the Fixing America's Surface Transportation Act (FAST-41). FAST-41 provides increased transparency and predictability by requiring Federal agencies to publish comprehensive permitting timetables for all covered projects. FAST-41 also provides procedures for modifying permitting timetables to address the unpredictability inherent in the environmental review and permitting process for significant infrastructure projects. To view the FAST-41 Permitting Dashboard for the Project, visit: www.permits.performance.gov/permitting-project/beacon-wind.

Scoping Process

This NOI commences the public scoping process to identify issues and potential alternatives for consideration in the Beacon Wind EIS. BOEM will hold virtual public scoping meetings at the times and dates described above under the **DATES** heading. Throughout the scoping process, Federal agencies, Tribes, State and local governments, and the public have the opportunity to help

BOEM identify significant resources and issues, impact-producing factors, reasonable alternatives (e.g., size, geographic, seasonal, or other restrictions on construction and siting of facilities and activities), and potential mitigation measures to be analyzed in the EIS, as well as to provide additional information.

As noted above, BOEM will use the NEPA process to comply with NHPA. BOEM will consider all written requests from individuals and organizations to participate as consulting parties under NHPA and, as discussed below, will determine who among those parties will be a consulting party in accordance with NHPA regulations.

NEPA Cooperating Agencies

BOEM invites other Federal agencies and State and local governments to consider becoming cooperating agencies and invites federally recognized Tribes to become cooperating Tribal governments in the preparation of this EIS. The Council on Environmental Quality (CEQ) NEPA regulations specify that cooperating agencies and governments are those with "jurisdiction by law or special expertise." Potential cooperating agencies should consider their authority and capacity to assume the responsibilities of a cooperating agency and should be aware that an agency's role in the environmental analysis neither enlarges nor diminishes the final decision-making authority of any other agency involved in the NEPA process.

BOEM will provide potential cooperating agencies with a written summary of expectations for cooperating agencies, including schedules, milestones, responsibilities, scope and detail of cooperating agencies' expected contributions, and availability of pre-decisional information. BOEM anticipates this summary will form the basis for a memorandum of agreement between BOEM and any non-Department of the Interior cooperating agency. Agencies should also consider the factors for determining cooperating agency status in the CEQ memorandum entitled "Cooperating Agencies in Implementing the Procedural Requirements of the National Environmental Policy Act," dated January 30, 2002. This document is available on the internet at: www.energy.gov/sites/prod/files/nepapub/nepa_documents/RedDont/G-CEQ-CoopAgenciesImplem.pdf. BOEM, as the lead agency, does not provide financial assistance to cooperating agencies.

Governmental entities that are not cooperating agencies will have

opportunities to provide information and comments to BOEM during the public input stages of the NEPA process.

NHPA Consulting Parties

Individuals and organizations with a demonstrated interest in the Project can request to participate as NHPA consulting parties under 36 CFR 800.2(c)(5) based on their legal or economic stake in historic properties affected by the Project.

Before issuing this NOI, BOEM compiled a list of potential consulting parties and invited them to become consulting parties. To become a consulting party, those invited must respond in writing by the requested response date.

Interested individuals and organizations that did not receive a written invitation can request to be consulting parties by writing to the staff NHPA contact at ICF International, Inc., the third-party EIS contractor supporting BOEM in its administration of this review. ICF's NHPA contact for this review is Alice Muntz at BeaconWind106@icf.com. BOEM will determine which interested parties should be consulting parties.

Comments

Federal agencies, Tribes, State and local governments, and other interested parties are requested to comment on the scope of this EIS, significant issues that should be addressed, and alternatives that should be considered.

Information on Submitting Comments

a. Freedom of Information Act

BOEM will protect privileged or confidential information that you submit when required by the Freedom of Information Act (FOIA). Exemption 4 of FOIA applies to trade secrets and commercial or financial information that is privileged or confidential. If you wish to protect the confidentiality of such information, clearly label it and request that BOEM treat it as confidential. BOEM will not disclose such information if BOEM determines under 30 CFR 585.114(b) that it qualifies for exemption from disclosure under FOIA. Please label privileged or confidential information "Contains Confidential Information" and consider submitting such information as a separate attachment.

BOEM will not treat as confidential any aggregate summaries of such information or comments not containing such privileged or confidential information. Information that is not labeled as privileged or confidential may be regarded by BOEM as suitable for public release.

b. Personally Identifiable Information (PII)

BOEM discourages anonymous comments. Please include your name and address as part of your comment. You should be aware that your entire comment, including your name, address, and any other personally identifiable information included in your comment, may be made publicly available. All comments from individuals, businesses, and organizations will be available for public viewing on *regulations.gov*.

For BOEM to consider withholding your PII from disclosure, you must identify any information contained in your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequences of the disclosure of information, such as embarrassment, injury, or other harm. Even if BOEM withholds your information in the context of this notice, your submission is subject to FOIA. If your submission is requested under FOIA, your information will only be withheld if a determination is made that one of FOIA's exemptions to disclosure applies. Such a determination will be made in accordance with the Department's FOIA regulations and applicable law.

c. Section 304 of the NHPA (54 U.S.C. 307103(a))

After consultation with the Secretary, BOEM is required to withhold the location, character, or ownership of historic resources if it determines that disclosure may, among other things, risk harm to the historic resources or impede the use of a traditional religious site by practitioners. Tribal entities should designate information that falls under section 304 of NHPA as confidential.

Request for Identification of Potential Alternatives, Information, and Analyses Relevant to the Proposed Action

BOEM requests data, comments, views, information, analysis, alternatives, or suggestions relevant to the Proposed Action from the public; affected Federal, Tribal, State, and local governments, agencies, and offices; the scientific community; industry; or any other interested party. Specifically, BOEM requests information on the following topics:

1. Potential effects that the Proposed Action could have on biological resources, including bats, birds, coastal fauna, finfish, invertebrates, essential fish habitat, marine mammals, and sea turtles.

2. Potential effects that the Proposed Action could have on physical resources and conditions including air quality, water quality, wetlands, and other waters of the United States.

3. Potential effects that the Proposed Action could have on socioeconomic and cultural resources, including commercial fisheries and for-hire recreational fishing, demographics, employment, economics, environmental justice, land use and coastal infrastructure, navigation and vessel traffic, other uses (marine minerals, military use, aviation), recreation and tourism, and scenic and visual resources.

4. Other possible reasonable alternatives to the Proposed Action that BOEM should consider, including additional or alternative avoidance, minimization, and mitigation measures.

5. As part of its compliance with NHPA section 106 and its implementing regulations (36 CFR part 800), BOEM seeks comment and input from the public and consulting parties regarding the identification of historic properties within the Proposed Action's area of potential effects, the potential effects on those historic properties from the activities proposed in the COP, and any information that supports identification of historic properties under NHPA. BOEM also solicits proposed measures to avoid, minimize, or mitigate any adverse effects on historic properties. BOEM will present available information regarding known historic properties during the public scoping period at www.boem.gov/renewable-energy/state-activities/beacon-wind. BOEM's effects analysis for historic properties will be available for public and consulting party comment with the draft EIS.

6. Information on other current or planned activities in, or in the vicinity of, the Proposed Action, their possible impacts on the Project, and the Project's possible impacts on those activities.

7. Other information relevant to the Proposed Action and its impacts on the human environment.

To promote informed decision-making, comments should be as specific as possible and should provide as much detail as necessary to meaningfully and fully inform BOEM of the commenter's position. Comments should explain why the issues raised are important to the consideration of potential environmental impacts and possible alternatives to the Proposed Action, as well as economic, employment, and other impacts affecting the quality of the human environment.

The draft EIS will include a summary of all alternatives, information, and

analyses submitted during the scoping process for consideration by BOEM and the cooperating agencies.

Authority: This NOI is published in accordance with NEPA, 42 U.S.C. 4321 *et seq.*, and 40 CFR 1501.9.

Karen J. Baker,

*Chief, Office of Renewable Energy Programs,
Bureau of Ocean Energy Management.*

[FR Doc. 2023-13918 Filed 6-29-23; 8:45 am]

BILLING CODE 4340-98-P

DEPARTMENT OF JUSTICE

[OMB Number 1122-0003]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Annual Progress Report for the STOP Formula Grants Program

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office on Violence Against Women (OVW), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 29, 2023.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Cathy Poston, Office on Violence Against Women, at (202) 514-5430 or Catherine.poston@usdoj.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Abstract: The STOP Violence Against Women Formula Grants Program was authorized through the Violence Against Women Act of 1994 (VAWA), 34 U.S.C. 10446 amended and reauthorized in 2000, 2005, 2013 and 2022. The STOP (Services, Training, Officers, and Prosecutors) Violence Against Women Formula Grant Program funding is awarded to States and territories. It enhances the capacity of local communities to develop and strengthen effective law enforcement and prosecution strategies to combat domestic violence, dating violence, sexual assault and stalking and to

develop and strengthen comprehensive, holistic victim services. The grant funds must be distributed by STOP State administrators to subgrantees according to a statutory formula. The annual progress reporting form is necessary for the Attorney General and STOP Formula Grant Program grantees and subgrantees to comply with Federal statutory reporting requirements. The information will be used for reports to Congress on the use of appropriated funds in support of the STOP Formula Grant Program. There are two sets of respondents- the STOP State administrators who allocate the STOP funds and the subgrantees who may include law enforcement agencies, prosecutors, officers, courts, and victim services organizations.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.
2. *The Title of the Form/Collection:* Annual Progress Report for the STOP Formula Grants Program.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Number: 1122–0003. U.S. Department of Justice, Office on Violence Against Women.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: State, local and Tribal governments. The obligation to respond is required to obtain/retain a benefit.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that it will take approximately one hour for roughly 2500 subgrantees to complete the relevant portion of the annual progress report.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The total annual hour burden to complete the annual progress report is 2,550 hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
STOP Annual Progress Report	2,556	1/annually	2,556	1 hour	2,556
<i>Unduplicated Totals</i>	<i>2,556</i>		<i>2,556</i>		<i>2,556</i>

If additional information is required contact: John R. Carlson, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: June 26, 2023.

John Carlson,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–13940 Filed 6–29–23; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0034]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; STOP Formula Grant Program Match Documentation Worksheet

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office on Violence Against Women (OVW), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 29, 2023.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Cathy Poston, Office on Violence Against Women, at (202) 514–5430 or Catherine.poston@usdoj.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information

are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Abstract: The STOP Violence Against Women Formula Grants Program was authorized through the Violence Against Women Act of 1994 (VAWA) and amended and reauthorized in 2000, 2005, 2013 and 2022. The STOP (Services, Training, Officers, and Prosecutors) Violence Against Women Formula Grant Program funding is awarded to States and Territories. It enhances the capacity of local communities to develop and strengthen effective law enforcement and prosecution strategies to combat domestic violence, dating violence, sexual assault and stalking and to develop and strengthen comprehensive, holistic victim services. The grant funds must be distributed by STOP State administrators to subgrantees according to a statutory formula. The Department of Justice's Office on Violence Against Women administers the STOP Formula Grant Program funds which are awarded to States and territories to enhance the capacity of local communities to develop and strengthen effective law enforcement and prosecution strategies to combat violent crimes against women and to develop and strengthen victim services in cases involving violent crimes against women. Each State and territory must allocate 25 percent for law enforcement, 25 percent for prosecutors, 30 percent for victim services (of which at least 10 percent must be distributed to culturally

specific community-based organizations), 5 percent to State and local courts, and 15 percent for discretionary distribution. VAWA provides for a 25 percent match requirement imposed on grant funds under the STOP Formula Grant Program. Thus, a grant made under this program may not cover more than 75 percent of the total costs of the project being funded. Under VAWA 2005, the State cannot require matching funds for a grant or subgrant for any Tribe, Territory, or victim service provider, regardless of funding allocation category. The State is exempted from matching the portion of the State award that goes to a victim service provider for victim services or that goes to Tribes. Territories are also exempted in full. States can receive additional waiver of match based on a petition to OVW and a demonstration of financial need. OVW will look at the time of closeout at the entities and purposes of funds and base the required match. The purpose of this information collection is to provide a worksheet for documenting the amount of matching funds required at the closeout of a specific fiscal year award under the STOP Formula Grant Program. The type of questions on the worksheet will include award number, award amount, amount of funds sub-awarded to victim service providers for victim services or to Tribes.

- Overview of This Information Collection
1. *Type of Information Collection:* Extension of a previously approved collection.

2. *The Title of the Form/Collection:* STOP Formula Grant Program Match Documentation Worksheet.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Number: 1122–0034. U.S. Department of Justice, Office on Violence Against Women.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: State, local and Tribal governments. The obligation to respond is required to obtain/retain a benefit.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that approximately 51 respondents will take approximately ten minutes to complete a STOP Formula Grant Program match documentation worksheet.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 8.5 hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Worksheet	51	1/annually	51	10 min	8.5
Unduplicated Totals	51		51		8.5

If additional information is required contact: John R. Carlson, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: June 26, 2023.

John Carlson,
Department Clearance Officer for PRA, U.S. Department of Justice.
[FR Doc. 2023–13937 Filed 6–29–23; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE
[OMB Number 1117–0010]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; U.S. Official Order Forms for Schedules I and II Controlled Substances DEA Form 222

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in

accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 29, 2023.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Courtney E. Mallon, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the

public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Abstract: The Controlled Substances Act (CSA) (21 U.S.C. 801–971) establishes a closed system of distribution for controlled substances. To this end, controlled substances are closely monitored and tightly regulated as they are distributed through the supply chain. One tool that helps to maintain the closed system of distribution is the CSA provision that states it “shall be unlawful for any person to distribute a controlled substance in schedules I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section.” 21 U.S.C. 828(a).

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.
2. *The Title of the Form/Collection:* U.S. Official Order Forms for Schedules I and II Controlled Substances.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

DEA Form: 222. The applicable component within the Department of Justice is the Drug Enforcement Administration, Office of Diversion Control.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: State, local and Tribal governments, private sector—businesses or not-for-profit institutions, Federal Government. The obligation to respond is mandatory per 21 CFR 1305.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 125,435 registrants participate in this information collection, taking an estimated average of 0.19 hours per registrant annually.

6. *An estimate of the total annual burden (in hours) associated with the collection:* DEA estimates the total public burden (in hours) associated with this collection to be 1,030,000 annual burden hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$130,350.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
DEA-222 (paper and online)	125,435	As needed, 42.651573/annually (calculated).	5,350,000	0.1925234 hour (calculated)	1,030,000
<i>Unduplicated Totals</i>	<i>125,435</i>		<i>5,350,000</i>		<i>1,030,000</i>

If additional information is required contact: John R. Carlson, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W-218, Washington, DC.

Dated: June 26, 2023.

John Carlson,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023-13933 Filed 6-29-23; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

[OMB Number 1110-0070]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Credit Card Payment Form (1-786)

AGENCY: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) Division, 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. The proposed information collection was previously published in the **Federal**

Register on April 5, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until July 31, 2023.

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: Larry E. Cotton-Zinn, Management and Program Analyst, FBI, CJIS, Criminal History Information and Policy Unit, BTC-3, 1000 Custer Hollow Road; Clarksburg, WV 26306; phone: 304-625-5590 or email fbi-iii@fbi.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the 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 1110-0070. 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 three (3) 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 of a previously approved collection.
2. *Title of the Form/Collection:* Credit Card Payment Form.
3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* 1110-0070, Form 1-786 Credit Card Payment Form; CJIS Division, FBI, DOJ.
4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Individuals interested in obtaining a copy of their identification

record contained in the FBI's Next Generation Identification System. The U.S. Department of Justice Order 556-773 directs the FBI to publish rules for the dissemination of arrest and conviction records to the subjects of such records upon request. This order resulted in a determination that 28 United States Code 534 does not prohibit the subjects of arrest and convictions records from having access to those records.

5. *Obligation to Respond:* Required to obtain or retain a benefit.

6. *Total Estimated Number of Respondents:* 28,039 yearly respondents.

7. *Estimated Time per Respondent:* 2 minutes.

8. *Frequency:* Varies.

9. *Total Estimated Annual Time Burden:* 934.6 hours.

10. *Total Estimated Annual Other Costs Burden:* \$0.

If additional information is required, contact: John R. Carlson, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W-218, Washington, DC 20530.

Dated: June 26, 2023.

John R. Carlson,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023-13935 Filed 6-29-23; 8:45 am]

BILLING CODE 4410-AT-P

DEPARTMENT OF LABOR

Employment and Training Administration

Request for Membership Nominations for the Advisory Committee on Apprenticeship (ACA)

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Acting Secretary of Labor (Secretary) has determined that the renewal of the Advisory Committee on Apprenticeship (hereinafter ACA or Committee) was necessary and in the public interest. The Department of Labor re-established the ACA Charter in 2021, and recently renewed its Charter, with revisions, on May 11, 2023. The Acting Secretary of Labor is now requesting nominations of qualified candidates to be considered for appointment to the ACA for the 2023–2025 membership term.

DATES: All ACA membership nominations must be received by

midnight no later than thirty (30) days from the date of this publication.

FOR FURTHER INFORMATION CONTACT: For any questions concerning the ACA nomination process, please contact Ms. Kenya Huckaby, Executive Assistant, Office of Apprenticeship, Employment and Training Administration, at Huckaby.Kenya@dol.gov, with a carbon copy to the ACA email box at advisorycommitteeonapprenticeship@dol.gov, telephone (202) 693-3795 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Registered Apprenticeship is a unique public private partnership that is highly dependent on the engagement and involvement of its stakeholders and partners for its ongoing operational effectiveness. Apart from the ACA, there is no single organization or group with the broad representation of employers, labor unions, and public entities available to consider the complexities and relationship of apprenticeship activities to other training efforts or to provide advice on such matters to the Secretary. It is particularly important to have such perspectives as DOL considers the expansion of registered apprenticeship and how best to fundamentally instill a permanent culture of inclusion in our workforce. The ACA's insights and recommendations on the best ways to address critical apprenticeship issues to meet the emerging needs of industry, labor organizations, and the public are critical. To learn additional information about the ACA please visit the ACA's landing page at: <https://www.apprenticeship.gov/advisory-committee-apprenticeship>.

Membership Composition: The ACA membership will consist of a range of 27–30 voting members with balanced representation of employers or industry associations, labor or joint labor-management organizations, and public entities and/or institutions. The ACA is solely advisory in nature, and will consider testimony, reports, comments, research, evidence, and existing practices as appropriate to develop recommendations for inclusion in its final recommendations to the Secretary. Members of the ACA serve without compensation, but will be allowed travel expenses, including per diem.

The final membership will come from a cross-section of individuals directly affected, interested, and qualified as appropriate to the nature and functions of the ACA. Each ACA member will serve at the pleasure of the Secretary for a specified term. The Secretary may also appoint members to fill any ACA vacancies for the unexpired portions of

the term. The National Association of State and Territorial Apprenticeship Directors will be represented by its current President on the public group. Additionally, the Secretary will appoint one of the public members to serve as the ACA Chairperson. After appointments are made, the ACA members will elect two co-chairs—one from the members representing the employers and one from the members representing the labor organizations. Representatives from the U.S. Departments of Commerce, Education, Energy, Health and Human Services, Housing and Urban Development, Transportation, and the Office of Personnel Management will be invited to serve as non-voting, *ex officio* members. The Acting Assistant Secretary of Labor for ETA will also serve as a non-voting, *ex officio* member.

Membership Terms: Members will be appointed for a specified term as designated by the Secretary. Appointments to vacancies occurring during the terms of such appointments will be for the unexpired portions of those terms. To the extent permitted by the Federal Advisory Committee Act and other laws, Committee membership should also be consistent with achieving the greatest impact, scope, and credibility among diverse stakeholders. The diversity in such membership includes, but is not limited to, race, gender, disability, sexual orientation, and gender identity.

Candidate Background Checks: In accordance with Departmental policy, all nominees under consideration to serve on the ACA will undergo a candidate background check to ensure there are no adverse legal or enforcement issues with the Department of Labor. Additionally, prior to appointment, final candidates will be required to complete form DLMS 1–900, Appendix A, a self-certification letter regarding criminal background. This form will be shared under separate cover as appropriate.

General Expectations for ACA Members: Candidates for consideration to be members of the ACA must be representative of a constituent base connected to apprenticeship activities. ACA Members should also have:

1. A demonstrated interest in the national apprenticeship system.
2. The ability and readiness to devote time and effort to attend all public ACA meetings, actively participate in ACA deliberations, advocate for the apprenticeship system, and participate in other member activities that are planned. Appointed ACA members will meet publicly on a quarterly basis. The

time commitment for these public meetings will range from two to four hours for a virtual meeting and one to two days for an in-person meeting. Meeting locations will vary and consist of a mix between in-person and virtual meetings. Attendance of these quarterly public meetings is mandatory except for limited circumstances. In such limited circumstances, an appointed ACA member will have the opportunity to send a delegate to participate in their place. Delegates should be capable of fully representing the interests of the appointed member and their constituency base. However, ACA membership is not transferable to a delegate and this opportunity should be utilized on a limited and as-needed basis to ensure the balance of perspectives of the appointed membership. Additional tasks of appointed ACA members may include participation in subcommittee meetings, site visits, and/or participation in other group engagement activities. Appointed members, or their delegate in limited circumstances, are expected to attend at least 50% of these additional tasks as scheduled.

3. The ability to analyze issues related to the apprenticeship model and to be a part of the deliberative process of advising the Secretary of Labor regarding innovative and emerging apprenticeship models and best practices.

4. The ability to remain objective and work well as a member of the Committee.

Nomination Process: Nominations received within thirty (30) days from the date of this publication will be given first consideration for membership on the ACA. Nominations received after thirty (30) days from the date of this publication, will be considered for nomination to the Committee as later vacancies occur. Information on how to submit a nomination for the ACA will be posted on the ACA's landing page under the membership tab at <https://www.apprenticeship.gov/advisory-committee-apprenticeship>. Nominees and/or Nominators will need to submit:

- A copy of the nominee's resume;
- A cover letter that provides the reason(s) for nominating the individual, including a description of the relevant experience and subject-matter expertise of that person concerning the development of a skilled workforce through quality apprenticeship programs, and the member category or categories (*i.e.*, employer, labor, or public) for which the individual would like to be considered. The cover letter must confirm that the ACA nominee has

agreed to be nominated and if appointed is willing to serve on the ACA.

- Contact information for the nominee (name, title, business address, business phone, and business email address. Optionally, nominees may also submit letters of support and their LinkedIn profile.

- Information related to the nominee's primary or secondary apprenticeship affiliations as well as industry representation(s).

Please do not include any information in the nomination submission that should not be publicly disclosed. In selecting ACA members, the Secretary will consider individuals nominated in response to this **Federal Register** notice, as well as other qualified individuals. Nominees will be appointed based upon their demonstrated qualifications, professional experience, and demonstrated knowledge of issues related to the scope and purpose of the ACA, as well as the need to obtain a diverse range of views on this important subject.

Brent Parton,

Acting Assistant Secretary for the Employment and Training Administration.

[FR Doc. 2023–13910 Filed 6–29–23; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Migrant and Seasonal Farmworker Monitoring Report and Complaint/Apparent Violation Form

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored 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 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 31, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Comments are invited on: (1) 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; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

Nicole Bouchet by telephone at 202–693–0213, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: ETA requires that staff must ensure a complainant (or his/her representative) submits a complaint on the Complaint/Apparent Violation Form or another complaint form prescribed or approved by the Department or submits complaint information. The Complaint/Apparent Violation Form must be used for all complaints, including complaints about unlawful discrimination. ETA Form 8429 is helpful because it identifies whether a complainant is a Migrant and Seasonal Farmworker which implicates additional actions that must be taken. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 2, 2023 (88 FR 13150).

This information collection is subject to the PRA. 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 the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Migrant and Seasonal Farmworker Monitoring Report and Complaint/Apparent Violation Form.

OMB Control Number: 1205–0039.

Affected Public: Private sector—individuals or households; State, local and Tribal governments.

Total Estimated Number of Respondents: 2,671.

Total Estimated Number of Responses: 5,666.

Total Estimated Annual Time Burden: 7,716 hours.

Total Estimated Annual Other Costs Burden: \$0.

(Authority: 44 U.S.C. 3507(a)(1)(D).)

Nicole Bouchet,

Senior PRA Analyst.

[FR Doc. 2023–13891 Filed 6–29–23; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 23–CRB–0007 AA]

Determination of Adjustment to Administrative Assessment To Fund Mechanical Licensing Collective

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Notice of commencement; request for petitions to participate; schedule.

SUMMARY: The Copyright Royalty Judges announce commencement of a proceeding to determine an adjustment to the administrative assessment that digital music providers and any significant nonblanket licensees must pay to fund the operations of the Mechanical Licensing Collective (MLC); set the date by which the MLC and the Digital Licensee Coordinator (DLC) must, and other eligible participants may, file a Petition to Participate and the accompanying \$150 filing fee; and announce the schedule for the proceeding and deadlines for submissions.

DATES: The commencement date of the proceeding is June 30, 2023. Petitions to Participate and the filing fee are due on or before July 17, 2023. The schedule for submissions and additional proceedings is set forth in the **SUPPLEMENTARY INFORMATION** section below.

ADDRESSES: Participants must file petitions to participate using the *online form* available on the Copyright Royalty Board's electronic filing application, eCRB, at <https://app.crb.gov/>. Participants must also file submissions in eCRB. See 37 CFR 303.5.

Instructions: All submissions must include the Copyright Royalty Board name and docket number, 23–CRB–0007

AA. All submissions and Petitions to Participate received will be posted without change on eCRB including any personal information provided.

Docket: For access to the docket, go to eCRB, the Copyright Royalty Board's electronic filing and case management system, at <https://app.crb.gov/>, and search for docket number 23–CRB–0007 AA.

FOR FURTHER INFORMATION CONTACT:

Anita Brown, CRB Program Specialist, (202) 707–7658, crb@loc.gov.

SUPPLEMENTARY INFORMATION: On May 31, 2023, the Mechanical Licensing Collective (MLC) and Digital Licensee Coordinator (DLC) filed with the Copyright Royalty Judges (Judges) a joint petition¹ to commence a proceeding to adjust the administrative assessment to be paid by digital music providers to fund the operating budget of the MLC along with a Joint Motion to Adopt Voluntary Agreement and Proposed Regulations. Section 115 of the Copyright Act requires the Judges, upon receipt of such a petition, to commence a proceeding by publication in the month of June of a notice in the **Federal Register** seeking Petitions to Participate. In the notice, the Judges must announce the schedule for submissions and further proceedings. 17 U.S.C. 115(d)(7)(D)(iv)(II); 37 CFR 355.2(b).

The Judges hereby announce commencement of the proceeding. Participation by the MLC and the DLC in the proceeding is required, and the participation of copyright owners, digital music providers, and significant nonblanket licensees in the proceeding is permitted. 17 U.S.C. 115(d)(7)(D)(iv)(II); 37 CFR 355.2(c)–(d). The Judges, therefore, direct the MLC and the DLC to file Petitions to Participate, request Petitions to Participate from any other eligible participant with a significant interest in the determination of the Administrative Assessment, and set a schedule for submissions and further proceedings.

Petitions To Participate

Parties filing Petitions to Participate must comply with the requirements of 37 CFR 355.2(e).

How To Submit Petitions To Participate

Petitioners must submit a filing fee of \$150 to the Copyright Royalty Board

¹ The most recent publication of a determination of the Administrative Assessment by the Judges was January 22, 2022 (86 FR 6568). Petitions to commence an adjustment proceeding may not be filed earlier than one year after that date and must be filed during the month of May, 37 CFR 355.2(b), and thus the joint petition was properly filed.

with their Petition to Participate, or the Judges will reject the petition.

Parties must file Petitions to Participate online through eCRB using the online form, including therein factual information sufficient to establish that the petitioner has a significant interest in the determination of the Administrative Assessment, pursuant to 17 U.S.C. 115(d)(7)(D)(iv)(II) and 37 CFR 355.2(e), and pay the filing fee by credit card using the payment portal on eCRB.

Any participant that is an individual may represent herself or himself. All other participants must be represented by counsel. In accordance with § 303.2 of the Judges' regulations, only attorneys who are members of the bar in one or more states or the District of Columbia and in good standing will be allowed to represent parties before the Copyright Royalty Judges. 37 CFR 303.2.

Schedule for Submissions and Further Proceedings

The schedule for submissions and further proceedings is as follows: the commencement date of the proceeding is June 30, 2023; the first negotiation period is June 30–August 29, 2023; written notification from the MLC and DLC regarding results of negotiations is due August 29, 2023; the opening submission from the MLC, with concurrent production of required documents and disclosures, is due September 28, 2023; the first discovery period is September 29–November 28, 2023; responsive submissions from the DLC and from other participants, with concurrent production of required documents and disclosures, are due December 28, 2023; the second discovery period is December 29, 2023–February 27, 2024; the second negotiation period is February 28–March 13, 2024; reply submissions from the MLC are due April 10, 2024; written notification from the MLC and DLC regarding results of negotiations is due March 13, 2024; the joint pre-hearing submission is due on April 15, 2024; a hearing on the record will begin on April 29, 2024. *See* 17 U.S.C. 115(d)(7)(D)(iv)(II), 37 CFR 355.2–355.4.

The Judges will address further procedural matters after Petitions to Participate are filed. *See* 37 CFR 355.2(f)–(g); 355.3(a), (h).

Dated: June 26, 2023.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2023–14023 Filed 6–28–23; 8:45 am]

BILLING CODE 1410–72–P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings

TIME AND DATE: The Members of the National Council on Disability (NCD) will hold a two-day in-person Council meeting on Wednesday, July 12, 2023, 9 a.m.–5:15 p.m. Eastern Daylight Time (EDT) and Thursday, July 13, 2023, 10 a.m.–12:30 p.m., EDT.

PLACE: This meeting will occur at the Willard Intercontinental Hotel, 1401 Pennsylvania Avenue NW, Washington, DC 20004. Attendees can use the accessible entrance to the hotel, located to the left of the main entrance and next to Café du Parc on Pennsylvania Avenue. The event will also be streamed live via Zoom videoconference for those not able to attend in person. Registration is not required. Details are available on NCD's event page at <https://ncd.gov/events/2023/upcoming-council-meeting>.

MATTERS TO BE CONSIDERED:

Day 1—Following welcome remarks and introductions, a panel will present on addressing health disparities through disability clinical care competency training; then a brief break; followed by a panel discussion regarding responding to health disparities of people with disabilities; an hour public comment session on experiences with healthcare barriers and bias; a lunch break; a presentation on NCD's project underway regarding germline editing and fetal medicine; a presentation on NCD's project underway on the inclusion of people with disabilities in clinical trials; and a presentation on NCD's 2023 progress report that is underway on income limits and asset limitations; followed by adjournment.

Day 2—Following welcome remarks and introductions, the Administration, Finance, and Operations team will provide updates to Council Members; followed by a Legislative Affairs and Outreach team update; a Policy team update; the Chairman's report; Executive Committee Report, including bylaws vote; Council Member report outs on community outreach; reminders on NCD's travel reimbursement process; and any old or new business, before adjourning.

Agenda: The times provided below are approximations for when each agenda item is anticipated to be discussed (all times Eastern Daylight Time):

Wednesday, July 12, 2023

9:00–9:05 a.m.—Welcome Greetings, Roll Call, Acceptance of Agenda
9:05–9:15—Chairman's Welcome and Framing Remarks for Meeting

9:15–10:45 a.m. Addressing Health Disparities through Disability Clinical Care Competency Training, Q&A from Council Members
10:45–11:00 a.m.—BREAK
11:00 a.m.–12:30 p.m.—Responding to Health Disparities of People with Disabilities—A Collaborative Effort
12:30–1:30 p.m.—Public Comment: Experiences with Healthcare Barriers and Bias
1:30–3:00 p.m. LUNCH BREAK
3:00–3:45 p.m.—Germline editing and fetal medicine project presentation, Q&A with Members
3:45–4:30 p.m.—Clinical trials report presentation, Q&A with Members
4:30–5:15 p.m.—NCD's 2023 Progress Report on asset limitations presentation, Q&A with Members
5:15 p.m.—Adjourn

Thursday, July 13, 2023

10:00–10:10 a.m.—Welcome and Call to Order, Roll Call, Approval of May 4 Council meeting minutes
10:10–10:20 a.m.—Administration, Finance, and Operations team update
10:20–10:30 a.m.—Legislative Affairs and Outreach team update
10:30 a.m.—11:00 a.m.—Policy team update
11:00–11:10 a.m.—Chairman's Report
11:10–11:40 a.m.—Executive Committee Report, including bylaws vote
11:40 a.m.–12:10 p.m.—Council Member report outs on community outreach/input
12:10–12:20 p.m.—AFO team reminders on reimbursement process
12:20–12:30 p.m.—Old/New Business
12:30 p.m.—Adjourn

Public Comment: Your participation during the public comment period provides an opportunity for us to hear from you—individuals, businesses, providers, educators, parents and advocates. Your comments are important in bringing to the Council's attention and issues and priorities of the disability community.

For the July 12 Council meeting, NCD will have an extended public comment period of one hour and requests comments from the public regarding experiences with healthcare barriers and bias for people with disabilities. Additional information on specifics of the topic is available on NCD's public comment page at <https://ncd.gov/public-comment>.

The Council will prioritize in-person commenters, but as time permits, will also receive public comment by video or audio over Zoom, and always accepts advance public comments via email. Due to the hybrid nature of the event, in-person presentations will be given priority.

To provide public comment during an NCD Council Meeting in any form (in-person or by Zoom), NCD now requires advanced registration by sending send an email to PublicComment@ncd.gov with the subject line "Public Comment" and your name, organization, state, and topic of comment included in the body of your email. Deadline for registration is July 11, 8:00 p.m. EDT. Please indicate if you are providing the comment in-person, over Zoom, or only submitting via email. All individuals desiring to make public comment are strongly encouraged to read NCD's guidelines for public comment in advance of the meeting at: <https://ncd.gov/public-comment>.

While public comment can be submitted on any topic over email, comments during the meeting should be specific to experiences with healthcare barriers and bias for people with disabilities.

CONTACT PERSON FOR MORE INFORMATION: Nicholas Sabula, Public Affairs Specialist, NCD, 1331 F Street NW, Suite 850, Washington, DC 20004; 202-272-2004 (V), or nsabula@ncd.gov.

Accommodations: ASL Interpreters will be provided in-room and included during the live streamed meeting, and CART has been arranged for this meeting and will be embedded into the Zoom platform as well as available via streamtext link. The web link to access CART (in English) is: <https://www.streamtext.net/player?event=NCD>.

If you require additional accommodations, please notify Stacey Brown by sending an email to sbrown@ncd.gov as soon as possible and no later than 24 hours prior to the meeting.

Due to last-minute confirmations or cancellations, NCD may substitute items without advance public notice.

Dated: June 27, 2023.

Anne C. Sommers McIntosh,
Executive Director.

[FR Doc. 2023-14022 Filed 6-28-23; 11:15 am]

BILLING CODE 8421-02-P

NUCLEAR REGULATORY COMMISSION

[NRC-2023-0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of July 3, 10, 17, 24, 31, August 7, 2023. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: <https://www.nrc.gov/public-involve/public-meetings/schedule.html>.

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301-287-0745, by videophone at 240-428-3217, or by email at Anne.Silk@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Closed.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301-415-1969, or by email at Wendy.Moore@nrc.gov.

MATTERS TO BE CONSIDERED:

Week of July 3, 2023

There are no meetings scheduled for the week of July 3, 2023.

Week of July 10, 2023—Tentative

Tuesday, July 11, 2023

10:00 a.m. Executive Branch Briefing on NRC International Activities (Closed Ex. 1 & 9)

Week of July 17, 2023—Tentative

There are no meetings scheduled for the week of July 17, 2023.

Week of July 24, 2023—Tentative

There are no meetings scheduled for the week of July 24, 2023.

Week of July 31, 2023—Tentative

There are no meetings scheduled for the week of July 31, 2023.

Week of August 7, 2023—Tentative

There are no meetings scheduled for the week of August 7, 2023.

CONTACT PERSON FOR MORE INFORMATION:

For more information or to verify the status of meetings, contact Wesley Held at 301-287-3591 or via email at Wesley.Held@nrc.gov.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: June 28, 2023.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2023-14105 Filed 6-28-23; 4:15 pm]

BILLING CODE 7590-01-P

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee; Virtual Public Meeting

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: According to the provisions of section 10 of the Federal Advisory Committee Act, notice is hereby given that a virtual meeting of the Federal Prevailing Rate Advisory Committee will be held on Thursday, July 20, 2023. There will be no in-person gathering for this meeting.

DATES: The virtual meeting will be held on July 20, 2023, beginning at 10:00 a.m. (ET).

ADDRESSES: The meeting will convene virtually.

FOR FURTHER INFORMATION CONTACT: Ana Paunoiu, 202-606-2858, or email pay-leave-policy@opm.gov.

SUPPLEMENTARY INFORMATION: The Federal Prevailing Rate Advisory Committee is composed of a Chair, five representatives from labor unions holding exclusive bargaining rights for Federal prevailing rate employees, and five representatives from Federal agencies. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

The Committee's primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the Office of Personnel Management.

Annually, the Chair compiles a report of pay issues discussed and concluded recommendations. These reports are available to the public. Reports for calendar years 2008 to 2020 are posted at <http://www.opm.gov/fprac>. Previous reports are also available, upon written request to the Committee.

The public is invited to submit material in writing to the Chair on Federal Wage System pay matters felt to be deserving of the Committee's attention. Additional information on these meetings may be obtained by contacting the Committee at Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 7H31, 1900 E Street NW, Washington, DC 20415, (202) 606-2858.

This meeting is open to the public, with an audio option for listening. This notice sets forth the agenda for the meeting and the participation guidelines.

Meeting Agenda. The tentative agenda for this meeting includes the following Federal Wage System items:

- The definition of Monroe County, PA.
- The definition of San Joaquin County, CA.
- The definition of the Salinas-Monterey, CA, wage area.
- The definition of the Puerto Rico wage area.

Public Participation: The July 20, 2023, meeting of the Federal Prevailing Rate Advisory Committee is open to the public through advance registration. Public participation is available for the meeting. All individuals who plan to attend the virtual public meeting to listen must register by sending an email to pay-leave-policy@opm.gov with the subject line "July 20, 2023" no later than Tuesday, July 18, 2023.

The following information must be provided when registering:

- Name.
- Agency and duty station.
- Email address.
- Your topic of interest.

Members of the press, in addition to registering for this event, must also RSVP to media@opm.gov by July 18, 2023.

A confirmation email will be sent upon receipt of the registration. Audio teleconference information for participation will be sent to registrants the morning of the virtual meeting.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2023–13986 Filed 6–29–23; 8:45 am]

BILLING CODE 6325–49–P

OFFICE OF PERSONNEL MANAGEMENT

[Docket ID: OPM–2023–0011]

Submission for Review: 3206–0162, Report of Medical Examination of Person Electing Survivor Benefits, OPM 1530

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an expiring information collection request (ICR), without change, titled "Report of Medical Examination of Person Electing Survivor Benefits," OPM 1530.

DATES: Comments are encouraged and will be accepted until August 29, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

—Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at <https://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to Cyrus.Benson@opm.gov or faxed to (202) 606–0910 or reached via telephone at (202) 936–0401.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0162). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of 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.

At the time of retirement, an employee or Member in good health may elect an insurable interest survivor annuity benefit on behalf of an eligible beneficiary. OPM Form 1530 is used to collect the information necessary to determine whether the employee or

Member is in good health so that OPM can determine whether the applicant is eligible to elect an insurable interest survivor annuity benefit.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Report of Medical Examination of Person Electing Survivor Benefits.

OMB Number: 3206–0162.

Frequency: On occasion.

Affected Public: Individuals or households.

Number of Respondents: 500.

Estimated Time per Respondent: 90 minutes.

Total Burden Hours: 750.

U.S. Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2023–13987 Filed 6–29–23; 8:45 am]

BILLING CODE 6325–38–P

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service®.

ACTION: Notice of modified systems of records.

SUMMARY: The United States Postal Service® (USPS) is proposing to revise one Customer Privacy Act System of Records (SOR). These modifications are being made to support an initiative to allow the linking of *USPS.com* accounts with approved third-party platforms used for the purchase of postage and fees for USPS shipping and mailing services.

DATES: These revisions will become effective without further notice on July 31, 2023, unless responses to comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be submitted via email to the Privacy and Records Management Office, United States Postal Service Headquarters (uspsprivacyfedregnotice@usps.gov). To facilitate public inspection, arrangements to view copies of written comments received may be made upon request.

FOR FURTHER INFORMATION CONTACT: Janine Castorina, Chief Privacy and Records Management Officer, Privacy and Records Management Office, via (uspsprivacyfedregnotice@usps.gov or 202–268–2000).

SUPPLEMENTARY INFORMATION:**I. Background**

This notice is in accordance with the Privacy Act requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition, or when the agency establishes a new system of records. The Postal Service has determined that Customer Privacy Act System of Records, USPS SOR 810.100, www.usps.com Registration, should be revised to support an initiative to allow the linking of *USPS.com* accounts with approved third-party platforms that provide additional options and convenience for customers to purchase postage and print mailing labels for USPS shipping and mailing services.

II. Rationale for Changes to USPS Privacy Act Systems of Records

The Postal Service has a long and storied history delivering for the American people. Technological advances have brought about significant changes to how people buy and sell a variety of products, allowing small businesses to reach an ever-increasing network of customers. The Postal Service is developing an initiative that supports innovation, grows revenue and meets changing marketplace needs.

One of the Postal Service's responses to this new commerce landscape is to enhance Click-n-Ship®, a Postal product that allows customers to print their own shipping labels right from their own computer. The Postal Service now seeks to upgrade Click-n-Ship's convenience, functionality and versatility by allowing *usps.com* users to link their Postal Service accounts with authorized third-party marketplaces that can assist business customers in meeting their USPS shipping and mailing needs.

III. Description of the Modified System of Records

To allow for the linking of accounts, this SOR will be revised as follows:

- Two new purposes, 17 and 18.
- One new category of records, 9.
- Additional elements in category of records 1.

Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed revisions has been sent to Congress and to the Office of Management and Budget for their evaluations. The Postal Service does not expect this amended system of records to have any adverse effect on individual privacy rights. USPS SOR 810.100 www.usps.com Registration is provided below in its entirety.

SYSTEM NAME AND NUMBER:

USPS 810.100, www.usps.com Registration.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Computer Operations Service Centers.

SYSTEM MANAGER(S):

Chief Customer and Marketing Officer and Executive Vice President, United States Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–5005, (202) 268–7536.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

39 U.S.C. 401, 403, and 404.

PURPOSE(S) OF THE SYSTEM:

1. To provide online registration with single sign-on services for customers.
2. To facilitate online registration, provide enrollment capability, and administer internet-based services or features.
3. To maintain current and up-to-date address information to assure accurate and reliable delivery and fulfillment of postal products, services, and other material.
4. To obtain accurate contact information in order to deliver requested products, services, and other material.
5. To authenticate customer login information for *usps.com*.
6. To permit customer feedback in order to improve *usps.com* or USPS products and services.
7. To enhance understanding and fulfillment of customer needs.
8. To verify a customer's identity when the customer establishes or attempts to access his or her account.
9. To identify, prevent, and mitigate the effects of fraudulent transactions.
10. To enhance the customer experience by improving the security of Change of Address (COA) and Hold Mail processes.
11. To protect USPS customers from becoming potential victims of mail fraud and identity theft.
12. To identify and mitigate potential fraud in the COA and Hold Mail processes.
13. To verify a customer's identity when applying for COA and Hold Mail services.
14. To provide online registration for Informed Address platform service for customers.
15. To authenticate customer login information for Informed Address platform services.
16. To verify the name and address of the sender or the authority of the sender's representative when submitting

an online International inquiry for a lost or damaged package on *usps.com*, such as the use of the International Assistant tool.

17. To link *usps.com* customer accounts with authorized third-party vendor accounts that allow customers to purchase postage and/or fees and print labels for USPS shipping and mailing services.

18. To facilitate the transmission of customer shipping information from third-party vendors to Click-n-Ship®.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Customers who register via the USPS website at *usps.com*.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. *Customer information:* Name; customer ID(s); company name; job title and role; home, business, and billing address; phone number(s) and fax number; email(s); URL; text message number(s) and carrier; Automated Clearing House (ACH) information; and account-linking identifier.
2. *Identity verification information:* Question, answer, username, user ID, password, email address, text message address and carrier, and results of identity proofing validation.
3. *Business specific information:* Business type and location, business IDs, annual revenue, number of employees, industry, nonprofit rate status, mail owner, mail service provider, PC postage user, PC postage vendor, product usage information, annual and/or monthly shipping budget, payment method and information, planned use of product, age of website, and information submitted by, or collected from, business customers in connection with promotional marketing campaigns.
4. *Customer preferences:* Preferences to receive USPS marketing information, preferences to receive marketing information from USPS partners, preferred means of contact, preferred email language and format, preferred on-screen viewing language, product and/or service marketing preference.
5. *Customer feedback:* Method of referral to website.
6. *Registration information:* Date of registration.
7. *Online user information:* Internet Protocol (IP) address, domain name, operating system versions, browser version, date and time of connection, Media Access Control (MAC) address, device identifier, information about the software acting on behalf of the user (*i.e.*, user agent), and geographic location.
8. *International Inquiries:* Name and address in Customer Registration

account profile used to match with Sender name and address or Sender's representative authority to file an international inquiry for a lost or damaged package.

9. *Click-n-Ship Account Linking Information*: Customer Address Details, Authentication, Customer Contact Name, Currency, Label Metadata, Marketplace Label data, Order ID, Order Status, Shipping Code, Value, IP Address, MAC Address, Device Type, Browser Type, OAuth accessToken, OAuth expiry, OAuth refreshToken, OAuth refreshTokenExpiry, OAuth tokenType, Marketplace Data ID, Marketplace Data Version, Marketplace Data Account Type, Marketplace Data Account Identifier, Marketplace Data Reference ID, Marketplace Data Labels.

RECORD SOURCE CATEGORIES:

Customers, Individual Sender and Sender's representative filing an international inquiry for lost or damaged packages.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Standard routine uses 1. through 7., 10., and 11. apply.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Automated database, computer storage media, and paper.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

By customer name, customer ID(s), phone number, mail, email address, IP address, text message address, and any customer information or online user information.

By tracking number for International package shipments for which an individual sender or sender's representative is filing an online International inquiry for loss or damage.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

1. ACH records are retained up to 2 years.
2. Records stored in the registration database are retained until the customer cancels the profile record, 3 years after the customer last accesses records, or until the relationship ends.
3. For small business registration, records are retained 5 years after the relationship ends.
4. Online user information may be retained for 6 months. Records existing on paper are destroyed by burning, pulping, or shredding. Records existing on computer storage media are destroyed according to the applicable USPS media sanitization practice.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records, computers, and computer storage media are located in controlled-access areas under supervision of program personnel. Access to these areas is limited to authorized personnel, who must be identified with a badge.

Access to records is limited to individuals whose official duties require such access. Contractors and licensees are subject to contract controls and unannounced on-site audits and inspections. Computers are protected by mechanical locks, card key systems, or other physical access control methods. The use of computer systems is regulated with installed security software, computer logon identifications, and operating system controls including access controls, terminal and transaction logging, and file management software. Online data transmissions are protected by encryption.

For small business registration, computer storage tapes and disks are maintained in controlled-access areas or under general scrutiny of program personnel. Access is controlled by logon ID and password as authorized by the Marketing organization via secure website. Online data transmissions are protected by encryption.

RECORD ACCESS PROCEDURES:

Requests for access must be made in accordance with the Notification Procedure above and USPS Privacy Act regulations regarding access to records and verification of identity under 39 CFR 266.5.

CONTESTING RECORD PROCEDURES:

See Notification Procedures and Record Access Procedures.

NOTIFICATION PROCEDURES:

Customers wanting to know if information about them is maintained in this system of records must address inquiries in writing to the system manager. Inquiries must contain name, address, and other identifying information.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

March 8, 2023, 88 FR 14400; December 27, 2018, 83 FR 66768; August 25, 2016, 81 FR 58542; June 30, 2016, 81 FR 42760; June 20, 2014, 79 FR 35389; January 23, 2014, 79 FR 3881; July 11, 2012, 77 FR 40921; October 24,

2011, 76 FR 65756; May 08, 2008, 73 FR 26155; April 29, 2005, 70 FR 22516.

Sarah Sullivan,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2023-13908 Filed 6-29-23; 8:45 am]

BILLING CODE 7710-12-P

POSTAL SERVICE

Notice of Availability of Draft Supplemental Environmental Impact Statement for Next Generation Delivery Vehicles Acquisitions

Pursuant to the requirements of the National Environmental Policy Act (NEPA) of 1969, the Council on Environmental Quality's regulations implementing NEPA (40 CFR parts 1500-1508), and the Postal Service's regulations for NEPA compliance set forth at 39 CFR part 775, the U.S. Postal Service announces availability of the Draft Supplemental Environmental Impact Statement (SEIS) which analyzes the environmental impacts of a range of alternatives for a modification to the Postal Service's February 23, 2022, Record of Decision (ROD) to purchase, over ten years, 50,000 to 165,000 purpose-built, right-hand drive vehicles—the Next Generation Delivery Vehicle (NGDV)—to replace existing delivery vehicles nationwide that are beyond the end of their service life. A minimum of 10 percent of those vehicles would be battery electric vehicles (BEVs).

As our Preferred Alternative, the Postal Service proposes in this Draft SEIS to modify the current ROD in three primary ways: (1) substantially increase the minimum BEV commitment to 62 percent, (2) reduce the total number of vehicles proposed for purchase at this time to 106,480, purchased over six years, and (3) include a mix of both NGDV and commercial-off-the-shelf (COTS) vehicles. This Draft SEIS also analyzes an NGDV-only Alternative with 62 percent BEV commitment, purchased over eight years, as well as a "No-Action" Alternative, which would proceed with the existing decision under the ROD.

The Postal Service is soliciting comments on the Draft SEIS during a 45-day public comment period. Comments should be received no later than August 14, 2023.

In addition, the Postal Service will also conduct a virtual public hearing on July 26, 2023. Registration information will be made available 15 days prior to the hearing date at the following website: <http://uspsngdveis.com/>.

Interested parties may view the Draft SEIS and the prior NGDV ROD at <http://>

uspsngdveis.com/. Interested parties may mail or deliver written comments, containing the name and address of the commenter, to: Mr. Davon Collins, Environmental Counsel, United States Postal Service, 475 L'Enfant Plaza SW, Office 6606, Washington, DC 20260–6201, or at NEPA@usps.gov. Note that comments sent by mail may be subject to delay due to Federal security screening. Faxed comments are not accepted. All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider confidential or inappropriate for public disclosure.

References

1. U.S. Postal Service, Notice of Availability of Record of Decision, Next Generation Delivery Vehicles Acquisitions (87 FR 14588; Mar. 15, 2022).
2. U.S. Postal Service, Notice of Intent to Prepare a Supplement to the Next Generation Delivery Vehicles Acquisitions Final Environmental Impact Statement (87 FR 35581; June 10, 2022).
3. U.S. Postal Service, Notice to Postpone Public Hearing and Extend Public Comment Period for Supplement to the Next Generation Delivery Vehicles Acquisitions Final Environmental Impact Statement (87 FR 43561; July 21, 2022).

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–13941 Filed 6–29–23; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–508, OMB Control No. 3235–0565]

Submission for OMB Review; Comment Request; Extension: Rule 482

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.*) (“Paperwork Reduction Act”), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget (“OMB”) a request for extension of the previously approved collection of information discussed below.

Like most issuers of securities, when an investment company (“fund”) ¹ offers

its shares to the public, its promotional efforts become subject to the advertising restrictions of the Securities Act of 1933 (15 U.S.C. 77) (the “Securities Act”). In recognition of the particular problems faced by funds that continually offer securities and wish to advertise their securities, the Commission has previously adopted advertising safe harbor rules. The most important of these is rule 482 (17 CFR 230.482) under the Securities Act, which, under certain circumstances, permits funds to advertise investment performance data, as well as other information. Rule 482 advertisements are deemed to be “prospectuses” under Section 10(b) of the Securities Act (15 U.S.C. 77j(b)).

Rule 482 contains certain requirements regarding the disclosure that funds are required to provide in qualifying advertisements. These requirements are intended to encourage the provision to investors of information that is balanced and informative, particularly in the area of investment performance. For example, a fund is required to include disclosure advising investors to consider the fund’s investment objectives, risks, charges and expenses, and other information described in the fund’s prospectus, and highlighting the availability of the fund’s prospectus. In addition, rule 482 advertisements that include performance data of open-end funds or insurance company separate accounts offering variable annuity contracts are required to include certain standardized performance information, information about any sales loads or other nonrecurring fees, and a legend warning that past performance does not guarantee future results. Such funds including performance information in rule 482 advertisements are also required to make available to investors month-end performance figures via website disclosure or by a toll-free telephone number, and to disclose the availability of the month-end performance data in the advertisement. The rule also sets forth requirements regarding the prominence of certain disclosures, requirements regarding advertisements that make tax representations, requirements regarding advertisements used prior to the effectiveness of the fund’s registration statement, requirements regarding the timeliness of performance data. In addition, rule 482(b) describes the information that is required to be included in an advertisement, including a cautionary statement under rule

Investment Company Act of 1940 (“Investment Company Act”) (15 U.S.C. 80a–1 *et seq.*) and business development companies.

482(b)(4) disclosing the particular risks associated with investing in a money market fund.

On October 26, 2022, the Commission adopted rule and form amendments that modernize the requirements for annual and semi-annual shareholder reports provided by open-end management investment companies.² The Commission also adopted amendments to the advertising rules for registered investment companies and business development companies to promote more transparent and balanced statements about investment costs. The advertising rule amendments require that investment company advertisements providing fee and expense figures include: (1) the maximum amount of any sales load or any other nonrecurring fee; and (2) the total annual expenses without any fee waiver or expense reimbursement arrangement. Under the amendments to rule 482, investment company fee and expense presentations in advertisements must include timely and prominent information about a fund’s maximum sales load (or any other nonrecurring fee) and gross total annual expenses, based on the methods of computation that the company’s Investment Company Act or Securities Act registration statement form prescribes for a prospectus.

Rule 482 advertisements must be filed with the Commission or, in the alternative, with the Financial Industry Regulatory Authority (“FINRA”).³ This information collection differs from many other federal information collections that are primarily for the use and benefit of the collecting agency.

Rule 482 contains requirements that are intended to encourage the provision to investors of information that is balanced and informative, particularly in the area of investment performance. The Commission is concerned that in the absence of such provisions fund investors may be misled by deceptive rule 482 advertisements and may rely on less-than-adequate information when determining in which funds they should invest money. As a result, the

² Tailored Shareholder Reports for Mutual Funds and Exchange-Traded Funds; Fee Information in Investment Company Advertisements, Investment Company Act Release No. 34731 (Oct. 26, 2022), 87 FR 72758 (Nov. 25, 2022) (the “Adopting Release”).

³ See note to rule 482(h) under the Securities Act, which states that “these advertisements, unless filed with [FINRA], are required to be filed in accordance with the requirements of § 230.497.” See also rule 24b–3 under the Investment Company Act (17 CFR 270.24b–3), which provides that any sales material, including rule 482 advertisements, shall be deemed filed with the Commission for purposes of Section 24(b) of the Investment Company Act upon filing with FINRA.

¹ “Investment company” refers to both investment companies registered under the

Commission believes it is beneficial for funds to provide investors with balanced information in fund advertisements in order to allow

investors to make better-informed decisions.

The table below summarizes our estimates associated with the

amendments to rule 482 that the Adopting Release addresses:

RULE 482 PRA ESTIMATES

	Internal initial hour burdens	Internal annual burden ¹	Wage rate ²	Internal time costs
FINAL ESTIMATES FOR RULE 482				
New general requirements re: fee and expense figure disclosure.	9 hours	6 hours ³	\$381 (blended rate for compliance attorney and senior programmer).	\$2,286.
Number of responses to rule 482 that include fee/expense figure disclosure.		× 36,492 ⁴ responses		× 36,492 responses.
Total burden of new requirements for fee and expense disclosure.		218,952 hours		\$83,420,712.
New requirements for disclosure of fee waivers/expense reimbursement arrangements.	6 hours	4 hours ⁵	\$381 (blended rate for compliance attorney and senior programmer).	\$1,524.
Number of responses to rule 482 that disclose fee waivers/expense reimbursement arrangements.		× 36,492 responses		× 36,492 responses.
Total burden of annual requirements for disclosure of fee waivers/expense reimbursement arrangements.		145,968 hours		\$55,613,808.
Total annual burden		364,920 hours		\$139,034,520.
TOTAL FINAL ESTIMATED BURDENS INCLUDING AMENDMENTS				
Current burden estimates		212,927 hours		\$74,098,735.
Revised burden estimate		577,847 hours		\$213,133,255.

Notes:

1. Includes initial burden estimates annualized over a 3-year period.

2. These PRA estimates assume that the same types of professionals would be involved in preparing advertisements (reflecting the proposed and final amendments to rule 482) that we believe otherwise would be involved in preparing a fund's advertisements. The Commission's estimates of the relevant wage rates are based on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association's *Office Salaries in the Securities Industry 2013*. The estimated figures are modified by firm size, employee benefits, overhead, and adjusted to account for the effects of inflation. See Securities Industry and Financial Markets Association, Report on Management & Professional Earnings in the Securities Industry 2013.

3. This estimate assumed that, after the initial 9 hours that an entity would spend on the proposed fee and expense disclosure, which we annualize over a 3-year period, the entity would incur 3 additional burden hours associated with ongoing compliance with these requirements per year. The estimate of 6 hours is based on the following calculation: ((9 initial hours/3) + 3 hours of additional ongoing burden hours) = 6 hours.

4. The Commission estimates that there was a total of 41,953 responses to rule 482 that either were filed with FINRA or with the Commission in 2021. Of those, the Commission estimates that 1,124 were responses from closed-end funds and BDCs, and that 2,816 were responses from variable insurance contracts. The number of responses filed with the SEC is based on the average number of responses filed with the Commission from 2019–2021. The Commission assumes that, moving forward, closed-end funds and BDCs will choose to use free writing prospectuses under rule 433, and also that variable insurance contracts will not be subject to the amendments to rule 482. Therefore, we exclude closed-end funds, BDCs, and variable insurance contracts from the total responses to rule 482 for purposes of this estimate. For purposes of estimating the burden of the final rules amendments, we estimate that 38,013 responses to rule 482 are filed annually. We estimate that approximately 96% of these rule 482 responses provide fee and expense figures in qualifying advertisements and would, therefore, be required to comply with the final rule amendments regarding such information (for example, ensuring that the fee and expense figures are presented in accordance with the prominence and timeliness requirements in the amendments to rule 482).

5. This estimate assumed that, after the initial 6 hours that an entity would spend on the proposed fee waiver and expense reimbursement requirements, which we annualized over a 3-year period, the entity would incur 2 additional burden hours associated with ongoing compliance with these requirements per year. The estimate of 4 hours is based on the following calculation ((6 initial hours/3) + 2 hours of additional ongoing burden hours) = 4 hours.

The table above summarizes our PRA initial and ongoing annual burden estimates associated with rule 482, as amended. In the aggregate, we estimate the total annual burden to comply with amended rule 482 to be 577,847 hours, at an average time cost of \$213,133,255.

The information provided under rule 482 will not be kept confidential. The

provision of information under rule 482 is necessary to obtain the benefits of the safe harbor offered by the rule.

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 and forms.

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 background documentation for this information collection at the following website: www.reginfo.gov. Find this particular

information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by July 31, 2023 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: June 27, 2023.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2023–13952 Filed 6–29–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97798; File No. SR–FINRA–2023–009]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA’s Trading Activity Fee

June 26, 2023.

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 June 23, 2023, the Financial Industry Regulatory Authority, Inc. (“FINRA”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as “establishing or changing a due, fee or other charge” under Section 19(b)(3)(A)(ii) of the Act³ and Rule 19b–4(f)(2) thereunder,⁴ which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to amend Section 1(f) of Schedule A to the FINRA By-Laws to exempt from the Trading Activity Fee (“TAF”) any transaction by

a proprietary trading firm that occurs on an exchange of which the proprietary trading firm is a member.

The text of the proposed rule change is available on FINRA’s website at <http://www.finra.org>, at the principal office of FINRA 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, FINRA 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. FINRA 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 a general matter, the most significant sources of FINRA’s funding are three core regulatory fees: the Gross Income Assessment; the TAF; and the Personnel Assessment.⁵ These regulatory fees are used to substantially fund FINRA’s regulatory activities, including examinations, financial monitoring, and FINRA’s policymaking, rulemaking, and enforcement activities.⁶ As discussed in FINRA’s prior *Regulatory Notices*, FINRA is proposing an exemption from one of FINRA’s regulatory fees—the TAF—for transactions by “proprietary trading firms,” which FINRA understands would include firms currently operating in compliance with existing SEA Rule 15b9–1 and that would be required to become FINRA members in light of the SEC’s proposed amendments to SEA Rule 15b9–1, as further discussed below.⁷ In this regard, FINRA proposes to define “proprietary trading firm” as a member that (i) trades exclusively its

own capital; (ii) does not have “customers,” which shall include any person, other than a broker or dealer, with whom the member engages, or within the past six months has engaged, in securities activities; and (iii) conducts all trading through the firm’s accounts by traders that are owners of, employees of, or contractors to the firm, or employees of an affiliate of the firm.

Under the Exchange Act, a registered broker-dealer must become a member of a national securities association (currently, FINRA is the sole national securities association) unless the broker-dealer effects transactions in securities solely on a national securities exchange of which it is a member.⁸ SEA Rule 15b9–1 provides an exemption to the requirement that a broker-dealer become a member of a national securities association if the broker-dealer (i) is a member of a national securities exchange, (ii) carries no customer accounts, and (iii) has annual gross income derived from purchases and sales of securities otherwise than on a national securities exchange of which it is a member in an amount no greater than \$1,000 (the \$1,000 limitation is known as the “*de minimis* allowance”).⁹ The \$1,000 gross income limitation does not apply to income derived from transactions for the dealer’s own account with or through another registered broker or dealer. Thus, for example, income derived from over-the-counter trades through an alternative trading system does not count toward the \$1,000 threshold. On July 29, 2022, the SEC proposed amendments to SEA Rule 15b9–1 to narrow the exemption from association membership.¹⁰

As discussed in the Proposing Release, the securities markets have evolved dramatically since the adoption of SEA Rule 15b9–1 and, today, the *de minimis* allowance is relied upon by proprietary trading firms that, in some cases, engage in substantial cross-exchange and off-exchange trading activity, yet they are not subject to FINRA oversight.¹¹ The SEC therefore proposed to eliminate the *de minimis* allowance and instead provide that a broker-dealer may effect transactions otherwise than on a national securities exchange of which it is a member in

⁵ See FINRA By-Laws, Schedule A, Section 1.

⁶ See Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–032).

⁷ FINRA believes that proprietary trading firms currently operating in compliance with existing SEA Rule 15b9–1 that would join FINRA due to the SEC’s proposed amendments to SEA Rule 15b9–1 would meet the proposed definition of “proprietary trading firm” and would qualify for the proposed exemption (assuming no changes to their business models that would alter their eligibility), as well as current FINRA members that meet the proposed definition. See also *infra* notes 37 and 39.

⁸ 15 U.S.C. 78o(b)(8).

⁹ 17 CFR 240.15b9–1.

¹⁰ See Securities Exchange Act Release No. 95388 (July 29, 2022), 87 FR 49930 (August 12, 2022) (“Proposing Release”). The SEC previously proposed to amend SEA Rule 15b9–1 in 2015. See Securities Exchange Act Release No. 74581 (March 25, 2015), 80 FR 18036 (April 2, 2015) (File No. S7–05–15) (“2015 Proposal”).

¹¹ See Proposing Release, *supra* note 10, 87 FR 49930, 49931.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b–4(f)(2).

only two narrow circumstances: (i) transactions that result solely from orders routed by the exchange of which the firm is a member to prevent trade-throughs consistent with Rule 611 of Regulation NMS or the Options Order Protection and Locked/Cross Market Plan; and (ii) transactions that are solely for the purpose of executing the stock leg of a stock-option order, subject to specified conditions.¹²

The SEC estimates that the proposed amendments to SEA Rule 15b9–1 would impact approximately 65 broker dealers that are not currently FINRA members.¹³ Thus, if adopted, the proposed amendments to SEA Rule 15b9–1 would require additional broker-dealers to become a member of FINRA (unless they limit their activities to the contours of the amended exemption from membership in a national securities association), and such member firms would become subject to FINRA regulatory fees, among other requirements.

Proprietary trading firms that potentially could become members of FINRA have expressed concern about the TAF in particular. FINRA notes that there currently are several exemptions from the TAF, including for transactions by floor brokers and for market making transactions subject to Section 11(a) of the Act.¹⁴ However, proprietary trading firms do not function as floor brokers and may only be registered market makers in some, but not all, of the securities that they trade. As a result, if the proposed amendments to SEA Rule 15b9–1 are adopted by the SEC, those proprietary trading firms that would become FINRA members would be subject to the TAF for much of their trading activity, including transactions on exchanges of which they are a member. The SEC noted specifically when proposing the amendments to SEA Rule 15b9–1 that FINRA may want to “evaluate its TAF to ensure that it appropriately reflects the activities of, and regulatory responsibilities towards, broker-dealer proprietary trading firms that would be required to join FINRA if the proposed amendments to [SEA] Rule 15b9–1 are adopted.”¹⁵ In light of the

SEC’s proposed amendments to SEA Rule 15b9–1, FINRA has considered the application and potential impact of the TAF to proprietary trading firms and has concluded that it is appropriate to provide an exemption from the TAF for all proprietary trading firms for transactions executed on an exchange of which the proprietary trading firm is a member.¹⁶ As FINRA regularly evaluates its fees to ensure appropriate funding for its regulatory mission, FINRA expects to evaluate the TAF—including with respect to proprietary trading firms—more broadly in the future.

FINRA has filed the proposed rule change for immediate effectiveness. FINRA will announce the implementation date of the proposed rule change in a *Regulatory Notice*. The implementation date will be no earlier than the date of adoption of the Commission’s amendments to SEA Rule 15b9–1 eliminating the *de minimis* allowance and no later than the effective date of any such amendments.¹⁷

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,¹⁸ which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls. FINRA believes that the proposed TAF exemption will result in an equitable allocation of fees to proprietary trading firms in accord with their activities and the regulatory resources to oversee them with respect to their trading activity on an exchange of which they are a member.

FINRA believes it is reasonable to propose this amendment in view of the fact that regulatory costs for firms that do not have customers are expected to be less than the cost to oversee the activity of firms with customers. FINRA also believes that it is appropriate to proceed with an exemption for proprietary trading firms with respect to their transactions on an exchange of which they are a member because FINRA anticipates that regulatory costs

largely will relate to overseeing such firms’ activity over the counter or across exchanges.

Under the proposal, proprietary trading firms (as defined in the proposed rule) that are current FINRA members would experience a reduction in their TAF assessments to the extent they conduct non-market making transactions executed on exchanges of which they are members. Proprietary trading firms that become FINRA members would incur a smaller TAF assessment than they otherwise would pay absent the proposal. Finally, FINRA believes that the proposal is reasonable in that the proposed exemption is clear, simple, and cost effective for firms to implement.

B. Self-Regulatory Organization’s Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

1. Regulatory Need

As discussed above, the SEC is proposing to amend SEA Rule 15b9–1 to narrow the scope of the exemption from FINRA membership. The proposed amendments to SEA Rule 15b9–1, if adopted, would generally require proprietary trading firms to become FINRA members if they engage in trading otherwise than on exchanges of which they are members.¹⁹

2. Economic Baseline

The economic baseline for FINRA’s proposed rule change consists of the regulatory framework under the SEC’s proposed amendments to SEA Rule 15b9–1, if adopted, as well as FINRA’s current TAF. In the Proposing Release, the SEC notes that, under the amended rule, a non-FINRA member firm that trades equities, options or fixed income securities off-exchange, or on exchanges of which it is not a member, can comply in four ways. One option is to join FINRA. The other options are to cease any off-exchange trading and either trade solely upon the exchanges of which the firm is already a member, or join additional exchanges, or cease trading securities altogether.²⁰ The discussion below briefly considers the benefits, costs and other economic impacts of the SEC proposed amendments to SEA Rule 15b9–1, as discussed by the SEC, to facilitate the

¹² See Proposing Release, *supra* note 10.

¹³ See Proposing Release, *supra* note 10, 87 FR 49930, 49954.

¹⁴ FINRA By-Laws, Schedule A, Section 1(b)(2)(F) and (G).

¹⁵ See Proposing Release, *supra* note 10, 87 FR 49930, 49943. In the 2015 Proposal, the SEC made a similar comment: “FINRA may need to consider reassessing the structure of its fees, including its Trading Activity Fee, in order to assure that it is fairly and equitably applied to many of the [non-FINRA member firms] that, as a result of the amendments to [SEA] Rule 15b9–1, may join

FINRA.” See 2015 Proposal, *supra* note 10, 80 FR 18036, 18044 n.95.

¹⁶ FINRA notes that, in addition to any other applicable FINRA fees, proprietary trading firms would incur a TAF obligation on transactions executed otherwise than on an exchange and on transactions executed on an exchange of which the firm is not a member. These transactions would be subject to the TAF under the existing fee structure and at existing rates.

¹⁷ See *supra* note 10.

¹⁸ 15 U.S.C. 78o–3(b)(5).

¹⁹ See *supra* notes 10–12 and accompanying text.

²⁰ See Proposing Release, *supra* note 10, 87 FR 49930, 49958.

consideration of the economic impacts of FINRA's proposed rule change to the TAF.

FINRA expects that some firms that are not currently FINRA members will apply for FINRA membership due to the SEC's modifications to SEA Rule 15b9-1, if adopted. These firms would maintain the ability to effect securities transactions on the same on and off exchange venues on which they currently effect such transactions. These firms would incur the one-time and ongoing costs of FINRA membership, including the TAF and other regulatory fees. The TAF would increase these firms' variable costs to trade, and the SEC notes that this may lead certain firms to reduce their trading both on-exchange and off-exchange.²¹ These firms may, however, mitigate some of the disincentive that comes from being liable for the TAF for trading on exchanges by registering as market makers.²² Membership by these firms in FINRA would provide more stable and uniform FINRA surveillance of off-exchange and cross-exchange trading activity than currently occurs.²³

Other non-FINRA member firms may choose to cease their off-exchange activity rather than join FINRA. Some of these firms may adjust their business models to trade solely upon the exchanges of which they are already a member or join additional exchanges upon which they wish to trade. However, since these firms may currently trade on exchanges of which they are not members, they may also cease trading on some of those exchanges.²⁴

The SEC also discusses how the changes non-FINRA member firms make to their business models to comply with the proposed amendments to SEA Rule 15b9-1 may affect other activities, including competition in the equity and U.S. Treasury securities markets, particularly for off-exchange liquidity provision.²⁵ As discussed above, non-FINRA member firms that join FINRA may reduce trading off-exchange and those that do not join FINRA will cease trading off-exchange, with similar impacts on their provision of off-exchange liquidity. Non-FINRA member firms may also reduce trading and liquidity provision on exchanges,

whether or not they join FINRA.²⁶ A loss in liquidity provision may impose costs on investors in the form of higher trading costs than they would otherwise realize.²⁷ However, current member firms may increase their activity and offset some of these impacts, both on and off-exchange.²⁸ The ultimate impact on liquidity, execution quality and trading volume for particular assets and trading venues is generally not determinate. Regarding the overall provision of liquidity to financial markets, however, the SEC argues that the effect of the proposed rule is not likely to be significant.²⁹

Current FINRA members, including proprietary trading firms, would not be directly affected by the SEC proposal.³⁰ However, to the extent that member firms currently compete with non-member firms that must become FINRA members or change their historical trading activities to avoid FINRA membership, the current members may benefit from having more uniform regulatory requirements among similarly situated competitors.

The SEC has estimated that there are approximately 65 broker-dealers registered with the Commission and exchange members that are not FINRA members. Each of these non-FINRA member firms will assess the costs and benefits of the options permitted by the amendments the SEC may make to SEA Rule 15b9-1. FINRA cannot determine the number of firms that may choose to become FINRA members or the likelihood or magnitude of any anticipated changes in trading behavior because of the proposed SEC rule amendments.³¹

FINRA estimates that approximately 66 member firms derive all or most of their revenue from proprietary trading, although not all of these firms would meet the proposed definition of "proprietary trading firm" based on their current business models.³² FINRA

understands that, of the 66 firms that clear their own trades, the TAF accounts for over 85% of the regulatory fees paid by these firms (GIA, PA and TAF). However, most of the 66 firms do not clear their own trades and so do not pay TAF directly to FINRA.³³ Whether these firms conduct trades subject to TAF and whether they reimburse their clearing firm for the TAF, is not known to FINRA. Overall, between 2015 and 2022, TAF as a proportion of regulatory fees received by FINRA ranged from 41% to 56%. For the member firms that are proprietary trading firms and conduct trades subject to TAF, this may be a closer approximation to the maximum share of their regulatory fees that would be subject to the proposed TAF exemption.

3. Economic Impacts

FINRA is proposing to amend the TAF to exempt all transactions by a FINRA member proprietary trading firm executed on an exchange of which it is a member.³⁴ The proposed rule change would directly impact member proprietary trading firms by providing them an exemption from the TAF for such transactions. These member proprietary trading firms include current FINRA members as well as those that would join FINRA due to the SEC's proposed amendments to SEA Rule 15b9-1. The FINRA proposed rule change may also impact the number of non-member proprietary trading firms that choose to apply for FINRA membership rather than use one of the other options for compliance (as described above). All comparisons below are relative to the baseline, and therefore assume that SEA Rule 15b9-1 is amended as proposed and that, notionally, firms have adjusted their business conduct taking into account the SEC proposed rule and market conditions, as described above.

a. Anticipated Benefits

FINRA believes that the proposed TAF exemption is clear and simple for firms to implement. In addition, the

for the proposed TAF exemption. Whether these firms would eliminate disqualifying activity, move it into a separate entity or decline to take the TAF exemption depends on the value of this activity and the extent to which the loss of scale economies in conducting the activity in a separate entity would affect the cost.

³³ See Trading Activity Fee Frequently Asked Questions, <https://www.finra.org/rules-guidance/guidance/faqs/trading-activity-fee> ("Data should be submitted as monthly aggregates at the clearing firm level" A100.6).

³⁴ As noted above, the TAF currently provides an exemption for proprietary transactions by a member firm effected on an exchange of which it is a member in its capacity as a specialist or market maker in the security on that exchange.

²¹ See Proposing Release, *supra* note 10, 87 FR 49930, 49958–60, 49965.

²² See Proposing Release, *supra* note 10, 87 FR 49930, 49960, 49965.

²³ See Proposing Release, *supra* note 10, 87 FR 49930, 49962.

²⁴ See Proposing Release, *supra* note 10, 87 FR 49930, 49967.

²⁵ See Proposing Release, *supra* note 10, 87 FR 49930, 49958.

²⁶ See Proposing Release, *supra* note 10, 87 FR 49930, 49959–60.

²⁷ See Proposing Release, *supra* note 10, 87 FR 49930, 49959. The SEC also states that the removal of liquidity from the market could either improve or degrade execution quality on off-exchange markets and reduced liquidity on exchanges can result in higher spreads and increased liquidity. *Id.* at 49960.

²⁸ See Proposing Release, *supra* note 10, 87 FR 49930, 49960.

²⁹ See *supra* note 28.

³⁰ See Proposing Release, *supra* note 10, 87 FR 49930, 49963.

³¹ FINRA notes that the SEC Proposal also discusses difficulties related to predicting changes in trading behavior and associated competitive impacts. See Proposing Release, *supra* note 10, 87 FR 49930, 49960.

³² Some of these 66 member firms may need to adjust their business models if they seek to qualify

proposed TAF exemption will likely dampen potential competitive effects and other market impacts as participants determine how to respond to proprietary trading firms' change in trading behaviors in response to the amendments to SEA Rule 15b9-1, while continuing to assess fees in a manner that is fair, reasonable, and equitably allocated among FINRA member firms. FINRA anticipates that, by reducing the fees associated with FINRA membership, the proposed TAF exemption may result in more proprietary trading firms joining FINRA. FINRA membership would allow these firms increased flexibility in where and how they trade.

Proprietary trading firms that are current FINRA members would experience a reduction in their TAF assessments to the extent they conduct non-market making transactions executed on exchanges of which they are members. Under the proposed TAF exemption, proprietary trading firms that become FINRA members would incur a smaller TAF assessment than they otherwise would pay absent the proposal. FINRA cannot determine the number of firms for which the proposed TAF exemption will have an impact on their determination of whether to become FINRA members and the likelihood or magnitude of any anticipated changes in trading behavior. There is significant diversity in the business models of proprietary trading firms. FINRA expects that the impacts of the exemption would depend on the level of trading activities proprietary trading firms conduct other than on the exchanges of which they are members. The impacts may also vary with the proportion of TAF to their overall FINRA membership costs. When TAF is expected to be a significant component of their membership costs, the proposed exemption is more likely to affect the firm's decision to become a FINRA member under the baseline.

b. Anticipated Costs

As discussed above, FINRA anticipates that the proposed TAF exemption may increase the number of proprietary trading firms that choose to become FINRA members relative to the baseline. The costs to these firms, like the benefits to these firms discussed above, are qualitatively the same as those incurred by proprietary trading firms that would choose to become FINRA members absent the proposed TAF exemption. These firms presumably choose to become FINRA members because the overall financial outcome is superior to that which would occur without joining FINRA and

complying with the SEC proposed rule by restricting their trades to exchanges of which they are members.

4. Other Economic Effects

Effects on Trading Activities

Proprietary trading firms that are current FINRA members may alter their trading strategies to take advantage of the proposed TAF exemption, which may impact the amount and allocation of trading activity among exchange and off-exchange trading venues from the baseline. Likewise, the existence of the TAF exemption may impact non-FINRA member firms' decision whether to become FINRA members, and thus also may impact the amount and allocation of trading activity among exchange and off-exchange trading venues from the baseline.

These potential changes in trading activity of proprietary trading firms may affect liquidity, execution quality and trading volume on the various trading venues. However, the extent and direction of the effect is generally not determinate and depends on how other market participants, including non-proprietary trading firms, respond to proprietary firms' actions.³⁵ To the extent the TAF exemption dampens a decrease in liquidity that may otherwise result as trading firms adjust to the amendments to SEA Rule 15b9-1, such an impact could help improve outcomes for investors seeking to trade, including lowering transaction costs or providing greater immediacy in trading relative to the baseline.

Effects on Competition

FINRA members that are proprietary trading firms may compete to provide liquidity with other FINRA members. Since the proposed TAF exemption is only available for proprietary trading firms, it could provide those firms with a competitive advantage over other members that engage in similar trading activity but do not qualify as proprietary trading firms by changing the relative costs of trading. However, this advantage would not be greater than what non-FINRA member proprietary trading firms currently experience (prior to the potential amendments of SEA Rule 15b9-1).

In addition, to the extent the proposed rule change leads to more proprietary trading firms joining FINRA, the proposed rule change may increase competition by having a more level playing field in terms of the costs associated with FINRA membership and regulatory requirements. As discussed

in the SEC Proposal, competition in liquidity provision may be distorted by inequalities in regulatory requirements.³⁶ With more uniform regulatory requirements and oversight due to the potential increase in FINRA membership, proprietary trading firms could compete more equitably to supply liquidity both on and off-exchange.

5. Alternatives Considered

FINRA considered alternatives to the exemption proposed in this proposed rule change. FINRA believes that the proposed TAF exemption is preferable to an exemption from other types of fees and is directly related to the impacts on the provision of liquidity that the SEC discusses in its proposal.

FINRA also considered other alternative changes to the TAF, including adjusting the overall rate of the TAF or implementing a tiered TAF structure based on trading activity or providing caps. However, such alternatives could likely be more costly to implement for both the affected firms and FINRA, compared to the proposed TAF exemption. Accordingly, FINRA believes that the simple structure in this proposed rule change would be more cost effective to implement. FINRA will have more information about the total fees paid by proprietary trading firms, and their impact on FINRA's regulatory programs and fees once these firms become FINRA members.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Following the SEC's 2015 Proposal to amend SEA Rule 15b9-1, FINRA published *Regulatory Notice 15-13* to solicit comment on a proposal to exclude from FINRA's TAF transactions by a proprietary trading firm on exchanges of which the firm is a member.³⁷ Four comment letters were received in response to the 2015 Notice.³⁸ Following the SEC's re-

³⁶ See Proposing Release, *supra* note 10, 87 FR 49930, 49960.

³⁷ See *Regulatory Notice 15-13* (May 2015) ("2015 Notice").

³⁸ Letter from Mary Ann Burns, Chief Operating Officer, FIA Principal Traders Group ("FIA PTG"), to Marcia E. Asquith, Corporate Secretary, FINRA, dated June 19, 2015 ("FIA PTG 2015 Letter"); Letter from Adam Nunes, Hudson River Trading LLC ("HRT"), to Marcia E. Asquith, Corporate Secretary, FINRA, dated June 19, 2015 ("HRT 2015 Letter"); Letter from Rory O'Kane, Chairman of the Board & James Toes, President and CEO, Security Traders Association ("STA"), to Marcia E. Asquith, Corporate Secretary, FINRA, dated June 19, 2015 ("STA Letter"); and Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, Securities Industry and Financial Markets

³⁵ See Proposing Release, *supra* note 10, 87 FR 49930, 49959.

proposal of amendments to SEA Rule 15b9–1 in December 2022, FINRA reopened the comment period for *Regulatory Notice* 15–13 by publishing *Regulatory Notice* 22–30.³⁹ Four additional comment letters were received in response to the 2022 Notice.⁴⁰ A copy of both *Regulatory Notices* are available on FINRA's website at <http://www.finra.org>. Copies of the comment letters received in response to both *Regulatory Notices* are also available on FINRA's website.

FINRA received four generally supportive comment letters in response to *Regulatory Notice* 15–13.⁴¹ All of these commenters also suggested expanding the proposed TAF exemption to cover additional proprietary trades. FINRA received three supportive⁴² and one unsupportive⁴³ comment letter in response to *Regulatory Notice* 22–30.

Supportive Comments

The FIA PTG 2023 Letter, HRT 2023 Letter, and Group One Letter stated that the proposed TAF exemption would help address the significant increase in costs that affected firms would otherwise face in light of the SEC's proposed amendments. HRT and FIA PTG further stated that the proposed exemption from TAF appropriately recognizes the differences in the activities between proprietary trading businesses and customer businesses, and the accompanying costs related to regulating each type of business.⁴⁴ Group One added that implementing the proposed TAF exemption would support the ability of proprietary trading firms to continue to provide liquidity in the least disruptive manner possible.⁴⁵ HRT, FIA PTG, and Group One also

asserted that implementing the TAF exemption would achieve an equitable allocation of fees and be in line with FINRA's actual cost of regulating its members.⁴⁶ SIFMA also generally supported the proposed TAF exemption and stated that FINRA should not assess TAF on any principal transactions executed on exchanges of which the firm is a member, regardless of the type of firm.⁴⁷

Requests for Modifications

The FIA PTG 2015 Letter and SIFMA Letter requested that the proposed TAF exemption be broadened to include all principal trades done on an exchange of which a firm is a member, rather than just trades by proprietary trading firms.⁴⁸ Similarly, STA recommended that FINRA “reduce the TAF rates for equity transactions by proprietary firms on over-the-counter and exchanges of which they are not a member.”⁴⁹

HRT proposed that all principal trades executed on any exchange be exempt from the TAF, adding that “off-exchange trades, as well as Agency and Riskless Principal trades executed on an exchange, should continue to be charged the TAF.”⁵⁰ HRT stated that, as proposed, the TAF exemption may discourage firms from engaging in customer-based business⁵¹ or, alternatively, could result in such firms operating multiple broker-dealers to avoid the proprietary firm business

incurring a TAF obligation on exempt exchange transactions.⁵²

As discussed above, FINRA believes that it is appropriate to proceed with an exemption from TAF for proprietary trading firms with respect to their transactions on an exchange of which they are a member because FINRA anticipates that regulatory costs largely will relate to overseeing such firms' activity over the counter or across exchanges.

The FIA PTG 2015 Letter requested that, should the TAF exemption be limited to “proprietary trading firms” as proposed, FINRA provide guidance regarding the scope of the term “proprietary trading firm” to clarify: (i) the scope of the term “customer” for purposes of the exemption, and (ii) the requirement that traders be owners of, employees of, or contractors to the firm. Specifically, the FIA PTG 2015 Letter requested that FINRA clarify that the criteria “does not have customers” only applies to customers that are engaged in transactions in securities that are subject to the TAF, and not to “non-securities transactions, fixed-income transactions, and other businesses such as stock-lending and licensing of technology.”⁵³ FIA PTG also asked that FINRA specify what time period is relevant for purposes of determining whether a firm is engaged in a customer business.⁵⁴ Further, FIA PTG requested that FINRA clarify that traders or other associated persons could be employed by an affiliate of the firm (rather than firm itself) without losing the ability to rely on the proposed exemption.⁵⁵ FIA PTG asserted that such employment arrangements are “a common structure” for such firms.⁵⁶

In response to these comments, FINRA is clarifying that the relevant activities for purposes of the proposed definition of “proprietary trading firm” are securities activities. The term “securities activities” would include transactions in any security (including fixed income) and also would include securities lending transactions. However, the term would not include non-securities activities such as licensing of technology or non-securities transactions. In addition, FINRA is modifying the definition of “proprietary trading firm” to clarify that “customer” would include “any person, other than a broker or dealer, with whom the member engages, or within the past six

Association (“SIFMA”), to Marcia E. Asquith, Corporate Secretary, FINRA, dated June 22, 2015 (“SIFMA Letter”).

³⁹ See *Regulatory Notice* 22–30 (December 2022) (“2022 Notice”).

⁴⁰ Letter from Adam Nunes, Hudson River Trading LLC, to Jennifer Piorko Mitchell, Office of the Corporate Secretary, FINRA, dated February 13, 2023 (“HRT 2023 Letter”); Letter from Joanna Mallers, Secretary, FIA PTG, to Jennifer Piorko Mitchell, Office of Corporate Secretary, FINRA, dated March 8, 2023 (“FIA PTG 2023 Letter”); Letter from John Kinahan, Chief Executive Officer, Group One Trading, LP (“Group One”), to Jennifer Piorko Mitchell, Office of Corporate Secretary, FINRA, dated March 15, 2023 (“Group One Letter”); and Letter from University of Pittsburgh, School of Law (“Pittsburgh University”) to Jennifer Piorko Mitchell, Office of Corporate Secretary, FINRA, dated March 17, 2023 (“University of Pittsburgh Letter”).

⁴¹ See FIA PTG 2015 Letter; HRT 2015 Letter; SIFMA Letter; and STA Letter.

⁴² See FIA PTG 2023 Letter; Group One Letter; and HRT 2023 Letter.

⁴³ See University of Pittsburgh Letter.

⁴⁴ See HRT 2023 Letter, at 1–2; FIA PTG 2023 Letter.

⁴⁵ See Group One Letter, at 1.

⁴⁶ See HRT 2023 Letter; FIA PTG 2023 Letter; and Group One Letter.

⁴⁷ See SIFMA Letter, at 2.

⁴⁸ Some comments also addressed the potential restructuring of the TAF as well as issues related to other FINRA fees. For example, STA suggested that FINRA reduce the current TAF rate for equity securities and, in particular, consider reducing the rate for over-the-counter and exchange trades by proprietary trading firms. SIFMA requested that FINRA review its fees more broadly and provide more transparency into how it uses and allocates the revenues it receives from fees and other sources of income. While these comments are not germane to the instant proposal—which seeks to provide an exemption from the TAF for a proprietary trading firm for transactions on an exchange of which it is a member—FINRA notes that it reviews its revenues as part of its budgeting process and revises fees as appropriate, both their application and their rates. In this regard, on October 14, 2020, FINRA amended various regulatory fees to increase the revenues that FINRA, as a not-for-profit self-regulatory organization, relies upon to fund its regulatory mission. The proposed fee increases were designed to better align FINRA's revenues with its costs while preserving the existing equitable allocation of fees among FINRA members. See Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2020–032).

⁴⁹ See STA Letter, at 4.

⁵⁰ See HRT 2015 Letter, at 2.

⁵¹ See *supra* note 50.

⁵² See *supra* note 50; see also FIA PTG 2015 Letter, at 3.

⁵³ See FIA PTG 2015 Letter, at 4.

⁵⁴ See *supra* note 53.

⁵⁵ See *supra* note 53, at 5.

⁵⁶ See *supra* note 53, at 5.

months has engaged, in securities activities.” FINRA believes that the six-month proposed timeframe will provide additional clarity as to the application of the rule as members’ businesses may evolve over time. Thus, for example, if a member restructures its business such that it ceases engaging in securities activities with customers, the member would be able to avail itself of the proposed proprietary trading firm exemption after a six-month period (assuming that the other conditions of the exemption are met). The six-month timeframe would be assessed on an ongoing basis; therefore, any securities activity with a customer would cause the firm to be ineligible for the exemption for six months from the time the firm ceases to engage in such customer activity. Finally, FINRA is proposing to include within the scope of “proprietary trading firm” a firm that (in addition to the other criteria) conducts all trading through the firm’s accounts by traders that are owners of, employees of, or contractors to the firm “or employees of an affiliate of the firm.”

Unsupportive Comments

Pittsburgh University stated that proprietary trading firms engage in significant trading in the marketplace, which pose a substantial risk to the market, and that there is a related cost for FINRA to supervise and oversee proprietary trading firm activity and that, therefore, FINRA should apply a TAF rate to proprietary trading firms that is proportional to the cost of regulating such firms.⁵⁷ Pittsburgh University also stated that “[w]hile the cost to regulate proprietary trading firms is less than the cost to regulate firms which trade on behalf of customers, proprietary trading firms should not be entirely exempt from the TAF when trading on an exchange on which they are members.”⁵⁸

FINRA agrees that regulating proprietary trading firm trading activity will involve a cost. For this reason, FINRA is not proposing to exempt proprietary trading firms from the TAF altogether. As discussed above, FINRA believes it is appropriate to exempt proprietary trading firms from the TAF for transactions on an exchange of

which they are a member because FINRA anticipates that regulatory costs largely will relate to overseeing such firms’ activity over the counter or across exchanges.

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) of the Act⁵⁹ and paragraph (f)(2) of Rule 19b-4 thereunder.⁶⁰ 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-FINRA-2023-009 in 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-FINRA-2023-009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written

communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FINRA. 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-FINRA-2023-009 and should be submitted on or before July 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶¹

J. Lynn Taylor,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-97800; File No. SR-MRX-2023-11]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Pricing Schedule at Options 7, Section 3

June 26, 2023.

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 June 12, 2023, Nasdaq MRX, LLC (“MRX” or “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.

⁶¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁵⁷ See University of Pittsburgh Letter, at 6.

⁵⁸ See University of Pittsburgh Letter. Pittsburgh University added that “[t]o exempt proprietary trading firms from TAFs would alter the balance between the TAF and other FINRA fees that fund FINRA’s operations, due to an increased cost in regulation without a similar increase of resources.”

⁵⁹ 15 U.S.C. 78s(b)(3)(f)(A).

⁶⁰ 17 CFR 240.19b-4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule at Options 7, Section 3 (Regular Order Fees and Rebates).

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/mrx/rules>, 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 Exchange included statements

concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's Pricing Schedule at Options 7, Section

3 (Regular Order Fees and Rebates). The Exchange initially filed the proposed pricing changes on June 1, 2023 (SR-MRX-2023-09). On June 12, 2023, the Exchange withdrew that filing and submitted this filing.

Background

Today, as set forth in Table 1 of Options 7, Section 3, the Exchange assesses the following maker/taker fees for regular orders in Penny and Non-Penny Symbols:

Market participant	Maker fee Tier 1	Maker fee Tier 2	Taker fee Tier 1	Taker fee Tier 2
Penny Symbols				
Market Maker ³	\$0.20	\$0.10	\$0.50	\$0.50
Non-Nasdaq MRX Market Maker (FarMM) ⁴	0.47	0.47	0.50	0.50
Firm Proprietary ⁵ /Broker-Dealer ⁶	0.47	0.47	0.50	0.50
Professional Customer ⁷	0.47	0.47	0.50	0.50
Priority Customer ⁸	0.00	0.00	0.00	0.00
Non-Penny Symbols				
Market Maker	0.35	0.20	1.10	1.10
Non-Nasdaq MRX Market Maker (FarMM)	0.90	0.90	1.10	1.10
Firm Proprietary/Broker-Dealer	0.90	0.90	1.10	1.10
Professional Customer	0.90	0.90	1.10	1.10
Priority Customer	0.00	0.00	0.00	0.00

Market participants are charged the above Tier 1 and Tier 2 maker/taker fees (or are eligible for free executions) if they meet the applicable tier thresholds

based on Total Affiliated Member or Affiliated Entity ADV⁹ in Table 3 of Options 7, Section 3. Market Makers may also alternatively qualify for these

fees if they meet the applicable tier thresholds based on Total Market Maker ADV¹⁰ in Table 3. Specifically:

Tiers	Total Affiliated Member or Affiliated Entity ADV	OR	Total Market Maker ADV
Tier 1 ...	executes 0.00% to less than 0.75% of Customer Total Consolidated Volume ¹¹ .		executes up to 0.10% of Customer Total Consolidated Volume which adds liquidity in Regular Orders.
Tier 2 ...	executes 0.75% or more of Customer Total Consolidated Volume.		executes more than 0.10% of Customer Total Consolidated Volume which adds liquidity in Regular Orders.

In addition, the Exchange currently offers Market Makers a number of ways to reduce their maker/taker fees

described above. First, Market Makers may qualify for reduced taker fees in Penny Symbols when trading against

Priority Customer orders in Penny Symbols entered by an Affiliated

³ The term "Market Makers" refers to "Competitive Market Makers" and "Primary Market Makers" collectively. See Options 1, Section 1(a)(21).

⁴ A "Non-Nasdaq MRX Market Maker" is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

⁵ A "Firm Proprietary" order is an order submitted by a Member for its own proprietary account.

⁶ A "Broker-Dealer" order is an order submitted by a Member for a broker-dealer account that is not its own proprietary account.

⁷ A "Professional Customer" is a person or entity that is not a broker/dealer and is not a Priority Customer.

⁸ A "Priority Customer" is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq MRX Options 1, Section 1(a)(36).

⁹ Total Affiliated Member or Affiliated Entity ADV means all ADV executed on the Exchange in all symbols and order types, including volume executed by Affiliated Members or Affiliated Entities. All eligible volume from Affiliated

Members or an Affiliated Entity will be aggregated in determining applicable tiers.

¹⁰ Total Market Maker ADV means all Market Maker ADV executed on the Exchange in all symbols and order types, including volume executed by Affiliated Members or Affiliated Entities. All eligible volume from Affiliated Members or an Affiliated Entity will be aggregated in determining applicable tiers.

¹¹ "Customer Total Consolidated Volume" means the total volume cleared at The Options Clearing Corporation in the Customer range in equity and ETF options in that month.

Member¹² or Affiliated Entity.¹³ In lieu of the \$0.50 per contract Tier 1/Tier 2 Market Maker Taker Fee, a Taker Fee of \$0.20 per contract applies instead when trading with Priority Customer orders in Penny Symbols entered by an Affiliated Member or Affiliated Entity. A Taker Fee of \$0.10 per contract applies instead when trading with Priority Customer orders in Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV¹⁴ of 0.20% to less than 0.75% Customer Total Consolidated Volume. A Taker Fee of \$0.00 per contract applies instead when trading with Priority Customer orders in Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV of 0.75% Customer Total Consolidated Volume or more.¹⁵

Second, Market Makers may currently qualify for reduced taker fees in Non-Penny Symbols when trading against Priority Customer orders in Non-Penny Symbols entered by an Affiliated

Member or Affiliated Entity. In lieu of the \$1.10 per contract Tier 1/Tier 2 Market Maker Taker Fee, a Taker Fee of \$0.90 per contract applies instead when trading with Priority Customer orders in Non-Penny Symbols entered by an Affiliated Member or Affiliated Entity. A Taker Fee of \$0.50 per contract applies instead when trading with Priority Customer orders in Non-Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV of 0.20% to less than 0.75% Customer Total Consolidated Volume. A Taker Fee of \$0.20 per contract applies instead when trading with Priority Customer orders in Non-Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV of 0.75% Customer Total Consolidated Volume or more.¹⁶

Third, Market Makers may qualify for a reduction in the Tier 1 and Tier 2 Maker Fees described above if the Market Maker has increased its volume

which adds liquidity in Penny Symbols as a percentage of Customer Total Consolidated Volume by at least 100% over the Member's December 2022 Market Maker volume which adds liquidity in Penny Symbols as a percentage of Customer Total Consolidated Volume. Market Makers that qualify will have their Tier 1 Maker Fee reduced to \$0.08 and their Tier 2 Maker Fee reduced to \$0.04. Market Makers with no volume in the Penny Symbol add liquidity segment for the month of December 2022 may qualify for the reduced Tier 1 and Tier 2 Maker Fees by having any new volume considered as added volume.¹⁷

Proposal 1: Amend Qualifying Tier Thresholds and Related Maker/Taker Pricing

The Exchange now proposes to amend the Table 3 qualifying tier thresholds in the following manner. First, the Exchange proposes to introduce new Tiers 3 and 4 and related maker/taker fees. Specifically, the Exchange proposes that Tiers 3 and 4 will have the following volume requirements:

Tiers	Total Affiliated Member or Affiliated Entity ADV	OR	Total Market Maker ADV
Tier 3 ...	executes 1.50% to less than 2.25% of Customer Total Consolidated Volume ¹⁸ .		executes more than 0.25% and up to 0.45% of Customer Total Consolidated Volume which adds liquidity in Regular Orders. ¹⁹
Tier 4 ...	executes 2.25% or more of Customer Total Consolidated Volume ²⁰ .		executes more than 0.45% of Customer Total Consolidated Volume which adds liquidity in Regular Orders.

As proposed, Market Makers that qualify for Tiers 3 and 4 will receive Penny Symbol maker rebates of \$0.05 per contract (Tier 3) and \$0.10 per contract (Tier 4). Additionally, Market Makers that qualify for Tiers 3 and 4 will be assessed a Penny Symbol taker fee of \$0.50 per contract in both tiers, which is the same Penny Symbol taker fee they are charged today in Tiers 1 and

2. The note 2 incentive will also apply to the Market Maker Tiers 3 and 4 taker fees in Penny Symbols, like they do today for Tiers 1 and 2. Specifically, the Exchange will also offer Market Makers the reduced Penny Symbol taker fees set forth in the note 2 incentive (in lieu of the \$0.50 per contract Tier 3/Tier 4 taker fee) if they trade against Priority Customer orders in Penny Symbols

entered by an Affiliated Member or Affiliated Entity.²¹

In Non-Penny Symbols, Market Makers that qualify for Tiers 3 and 4 will be charged maker fees of \$0.15 per contract (Tier 3) and \$0.10 per contract (Tier 4). Additionally, Market Makers that qualify for Tiers 3 and 4 will be assessed a Non-Penny Symbol taker fee of \$1.10 per contract in both tiers,

¹² An "Affiliated Member" is a Member that shares at least 75% common ownership with a particular Member as reflected on the Member's Form BD, Schedule A.

¹³ An "Affiliated Entity" is a relationship between an Appointed Market Maker and an Appointed OFF for purposes of qualifying for certain pricing specified in the Pricing Schedule. Market Makers and OFFs are required to send an email to the Exchange to appoint their counterpart, at least 3 business days prior to the last day of the month to qualify for the next month. The Exchange will acknowledge receipt of the emails and specify the date the Affiliated Entity is eligible for applicable pricing, as specified in the Pricing Schedule. Each Affiliated Entity relationship will commence on the 1st of a month and may not be terminated prior to the end of any month. An Affiliated Entity relationship will automatically renew each month until or unless either party terminates earlier in writing by sending an email to the Exchange at least 3 business days prior to the last day of the month to terminate for the next month. Affiliated Members

may not qualify as a counterparty comprising an Affiliated Entity. Each Member may qualify for only one (1) Affiliated Entity relationship at any given time.

¹⁴ Total Affiliated Member or Affiliated Entity Priority Customer ADV means all Priority Customer ADV executed on the Exchange in all symbols and order types, including volume executed by Affiliated Members or Affiliated Entities. All eligible volume from Affiliated Members or an Affiliated Entity will be aggregated in determining applicable tiers.

¹⁵ See Options 7, Section 3, Table 1, note 2 ("note 2 incentive").

¹⁶ See Options 7, Section 3, Table 1, note 3 ("note 3 incentive").

¹⁷ See Options 7, Section 3, Table 1, note 6 ("note 6 incentive"). The note 6 incentive will be available to Market Makers until June 30, 2023.

¹⁸ 1.50% of Customer Total Consolidated Volume is approximately 517,800 contracts per day.

¹⁹ 0.25% of Customer Total Consolidated Volume is approximately 86,300 contracts per day. 0.45%

of Customer Total Consolidated Volume is approximately 155,300 contracts per day.

²⁰ 2.25% of Customer Total Consolidated Volume is approximately 776,700 contracts per day.

²¹ As discussed above, the note 2 incentive currently provides that a Taker Fee of \$0.20 per contract applies instead when trading with Priority Customer orders in Penny Symbols entered by an Affiliated Member or Affiliated Entity. A Taker Fee of \$0.10 per contract applies instead when trading with Priority Customer orders in Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV of 0.20% to less than 0.75% Customer Total Consolidated Volume. A Taker Fee of \$0.00 per contract applies instead when trading with Priority Customer orders in Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV of 0.75% Customer Total Consolidated Volume or more.

which is the same Non-Penny Symbol taker fee they are charged today in Tiers 1 and 2. The note 3 incentive will also apply to Market Maker Tiers 3 and 4 taker fees in Non-Penny Symbols, like they do today for Tiers 1 and 2. Specifically, the Exchange will also offer Market Makers the reduced Non-Penny Symbol taker fees set forth in the note 3 incentive (in lieu of the \$1.10 per contract Tier 3/Tier 4 taker fee) if they trade against Priority Customer orders in Non-Penny Symbols entered by an Affiliated Member or Affiliated Entity.²²

For non-Priority Customers except Market Makers, the Exchange will continue to assess the same maker/taker

fees in Tiers 3 and 4 for Penny and Non-Penny Symbols as the non-Priority Customer maker/taker fees in Tiers 1 and 2 today. Specifically, all non-Priority Customers other than Market Makers will be assessed the Penny Symbol maker fee of \$0.47 per contract and Penny Symbol taker fee of \$0.50 per contract across Tiers 1–4. Additionally, all non-Priority Customers except Market Makers will be assessed the Non-Penny Symbol maker fee of \$0.90 per contract and Penny Symbol taker fee of \$1.10 per contract across Tiers 1–4.

As it relates to Priority Customers, the Exchange will continue to assess no maker fees in Tiers 3 and 4 in both

Penny and Non-Penny Symbols, identical to the Priority Customer Tiers 1 and 2 maker fees today. For the taker fees in both Penny and Non-Penny Symbols, the Exchange will charge Priority Customers \$0.15 per contract in Tier 3 and \$0.10 per contract in Tier 4.

Second, the Exchange proposes to modify the existing qualifying tier thresholds and related maker/taker pricing for Tiers 1 and 2. As it relates to the qualifying tier thresholds, the Exchange proposes to amend the Tier 2 qualifications as follows:

Tiers	Total Affiliated Member or Affiliated Entity ADV	OR	Total Market Maker ADV
Tier 2 ...	executes 0.75% to less than 1.50% of Customer Total Consolidated Volume ²³ .		executes more than 0.10% and up to 0.25% of Customer Total Consolidated Volume which adds liquidity in Regular Orders.

As described above, the Tier 2 Total Affiliated Member or Affiliated Entity ADV threshold and the Tier 2 Total Market Maker ADV threshold will both be modified to accommodate the respective new thresholds.²⁴ The Tier 1 qualifications will remain unchanged under this proposal.

For the related Tier 1 and Tier 2 maker/taker fees, the Exchange proposes to modify those fees for Market Makers and Priority Customers in a number of ways. For Market Makers, the Exchange proposes to decrease the Penny Symbol maker fees in Tier 1 and Tier 2 from \$0.20 to \$0.10 per contract (Tier 1) and from \$0.10 to \$0.00 per contract (Tier 2). No other changes are being proposed to the remaining Tiers 1 and 2 maker/taker fees for Market Makers.

As it relates to Priority Customers, the Exchange proposes to begin charging those market participant orders taker fees in Tiers 1 and 2. Specifically, Priority Customers will be charged taker fees of \$0.15 per contract in both Tiers 1 and 2 for Penny Symbols. For Non-Penny Symbols, the Exchange proposes

to charge Priority Customers taker fees of \$0.35 per contract (Tier 1) and \$0.25 per contract (Tier 2).

While the maker/taker fees in Table 1 of Options 7, Section 3 for the majority of market participants (*i.e.*, Non-Nasdaq MRX Market Makers, Firm Proprietary/Broker-Dealers, and Professional Customers) will not be impacted by the changes proposed above, the proposal will impact maker pricing for Market Makers and taker pricing for Priority Customers.²⁵ In particular, qualifying Market Makers will see a decrease in their current Tier 1 and Tier 2 maker fees in Penny Symbols, and be eligible to receive the new Tier 3 and Tier 4 maker rebates in Penny Symbols. Additionally, qualifying Market Makers will be eligible for the new Tier 3 and Tier 4 maker fees in Non-Penny Symbols, which will be lower than the current Non-Penny Symbol Tier 1 and Tier 2 maker fees.²⁶ Furthermore, the Exchange will start charging Priority Customers taker fees in Tiers 1–4 across all symbols traded on the Exchange in the manner described above. Today,

Priority Customers are not assessed any taker fees under the Table 1 pricing schedule.²⁷

Proposal 2: Eliminate Note 6 Incentive

The Exchange proposes to eliminate the note 6 incentive described above. This temporary incentive was first introduced to encourage Market Makers to engage in substantial amounts of liquidity adding activity in Penny Symbols on the Exchange, as well as to grow substantially the extent to which they do so relative to a recent benchmark month.²⁸ The Exchange does not believe that the note 6 incentive has had the intended effect, and is therefore eliminating it before the expiration date of June 30, 2023 in order to redirect resources into other pricing programs intended to incentivize increased order flow.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

²² As discussed above, the note 3 incentive currently provides that a Taker Fee of \$0.90 per contract applies instead when trading with Priority Customer orders in Non-Penny Symbols entered by an Affiliated Member or Affiliated Entity. A Taker Fee of \$0.50 per contract applies instead when trading with Priority Customer orders in Non-Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV of 0.20% to less than 0.75% Customer Total Consolidated Volume. A Taker Fee of \$0.20 per contract applies instead when trading with Priority Customer orders in Non-Penny Symbols entered by an Affiliated Member or Affiliated Entity if the Member has a Total Affiliated Member or Affiliated Entity Priority Customer ADV of 0.75% Customer Total Consolidated Volume or more.

²³ 0.75% of Customer Total Consolidated Volume is approximately 258,900 contracts per day.

²⁴ As discussed above, the new Tier 3 Total Affiliated Member or Affiliated Entity ADV threshold will require Members to execute 1.50% to less than 2.25% of Customer Total Consolidated Volume. The new Tier 3 Total Market Maker ADV threshold will require Market Makers to execute more than 0.25% and up to 0.45% of Customer Total Consolidated Volume which adds liquidity in Regular Orders.

²⁵ In particular, these market participants will continue to be uniformly charged the same maker fees of \$0.47 per contract (Penny Symbols) and \$0.90 per contract (Non-Penny Symbols), regardless of tier achieved. In addition, they will continue to be uniformly charged the same taker fees of \$0.50 per contract (Penny Symbols) and \$1.10 per

contract (Non-Penny Symbols), regardless of tier achieved.

²⁶ However, as discussed above, Market Makers will continue to be uniformly charged the same taker fees \$0.50 per contract (Penny Symbols) and \$1.10 per contract (Non-Penny Symbols), regardless of tier achieved. They will also continue to be eligible for the note 2 incentive (Penny Symbols) and note 3 incentive (Non-Penny Symbols), regardless of tier achieved.

²⁷ However, as discussed above, Priority Customers will continue to not be charged any maker fees pursuant to the Table 1 pricing schedule under this proposal.

²⁸ See Securities Exchange Act Release No. 97148 (March 15, 2023), 88 FR 17068 (March 21, 2023) (SR-MRX-2023-07).

of the Act,²⁹ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,³⁰ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its schedule of credits are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition v. Securities Exchange Commission*, the D.C. Circuit stated as follows: "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . ." ³¹

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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." ³²

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of sixteen options exchanges to which market participants may direct their order flow.

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

Proposal 1: Amend Qualifying Tier Thresholds and Related Maker/Taker Pricing

The Exchange believes that its proposal to amend the qualifying tier thresholds and related maker/taker pricing are reasonable for several reasons. The Exchange believes that the modified volume threshold in Tier 2 and the new volume thresholds in Tiers 3 and 4 are reasonably designed to encourage Market Makers and Priority Customers to increase their liquidity adding activity to qualify for lower maker fees or maker rebates (for Market Makers only) and to increase their liquidity removing activity to qualify for the lower taker fees (for Priority Customers only).³³ The Exchange believes that adding new Tiers 3 and 4 will encourage Market Makers and Priority Customers to strive to achieve the higher tiers by submitting the requisite amount of order flow. An overall increase in activity would deepen the Exchange's liquidity pool, support the quality of price discovery, and promote market quality to benefit of all market participants.

The Exchange also believes that the proposed maker/taker pricing in Table 1 of Options 7, Section 3 is reasonable for the reasons that follow. First, the Exchange believes that it is reasonable to assess qualifying Market Makers lower maker fees or maker rebates, depending on the tier achieved, in the manner described above.³⁴ The proposed structure will encourage Market Makers to increase their liquidity providing activity on the Exchange, which would support the

quality of price discovery on the Exchange, provide additional liquidity for incoming orders, and create additional opportunities for market participants to trade. Second, the Exchange believes its proposal to begin charging Priority Customers taker fees in Tiers 1–4 across all symbols traded on the Exchange in the manner described above is reasonable because Priority Customers will continue to be assessed the lowest taker fees compared to any other market participant on the Exchange.³⁵ Accordingly, the Exchange believes that the proposed taker fees will remain attractive and continue to incentivize more executions in Priority Customer orders on the Exchange.

The Exchange further believes that the proposed changes to the qualifying tier thresholds and related maker/taker pricing in the manner described above are equitable and not unfairly discriminatory as the proposed changes will apply uniformly to all similarly situated participants. The maker/taker fees in Table 1 of Options 7, Section 3 for the majority of market participants (*i.e.*, Non-Nasdaq MRX Market Makers, Firm Proprietary/Broker-Dealers, and Professional Customers) will not be impacted by the Exchange's proposal as they will continue to be charged the same pricing they are assessed today, regardless of tier achieved.³⁶ The proposal, however, will impact maker pricing for Market Makers and taker pricing for Priority Customers, which will ultimately result in these market participants receiving more favorable pricing compared to other market participants under amended Table 1 of Options 7, Section 3. The Exchange believes the proposed structure continues to be equitable and not unfairly discriminatory as the Exchange has historically provided Market Makers and Priority Customers with more favorable pricing. Furthermore, Market Makers, unlike other market participants add value to the Exchange through quoting obligations and their commitment of capital. Additionally, Priority Customer liquidity benefits all market participants by providing more trading opportunities, which attracts market makers. An increase in the

³³ As discussed above, Non-Nasdaq MRX Market Makers, Firm Proprietary/Broker-Dealers, and Professional Customers will continue to be uniformly charged the same maker fees of \$0.47 per contract (Penny Symbols) and \$0.90 per contract (Non-Penny Symbols), regardless of tier achieved. In addition, they will continue to be uniformly charged the same taker fees of \$0.50 per contract (Penny Symbols) and \$1.10 per contract (Non-Penny Symbols), regardless of tier achieved.

³⁴ In particular, qualifying Market Makers will see a decrease in their current Tier 1 and Tier 2 maker fees in Penny Symbols, and be eligible to receive the new Tier 3 and Tier 4 maker rebates in Penny Symbols. Additionally, qualifying Market Makers will be eligible for the new Tier 3 and Tier 4 maker fees in Non-Penny Symbols, which will be lower than the current Non-Penny Symbol Tier 1 and Tier 2 maker fees.

³⁵ As proposed, Priority Customers will now be assessed Penny Symbol taker fees of \$0.15 per contract (Tiers 1–3) and \$0.10 per contract (Tier 4). For all non-Priority Customers, this Penny Symbol taker fee is \$0.50 per contract (regardless of tier achieved). Additionally, Priority Customers will now be assessed Non-Penny Symbol taker fees of \$0.35 per contract (Tier 1), \$0.25 per contract (Tier 2), \$0.15 per contract (Tier 3), and \$0.10 per contract (Tier 4). For all non-Priority Customers, this Non-Penny Symbol taker fee is \$1.10 per contract.

³⁶ See *supra* note 25.

²⁹ 15 U.S.C. 78f(b).

³⁰ 15 U.S.C. 78f(b)(4) and (5).

³¹ *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

³² Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants, to the benefit of all market participants.

Proposal 2: Eliminate Note 6 Incentive

The Exchange believes that its proposal to eliminate the note 6 incentive described above is reasonable because this temporary incentive has not had its intended effect of incentivizing Market Makers to increase their liquidity adding activity in Penny Symbols on the Exchange over the stipulated time period. As such, the Exchange is eliminating the note 6 incentive in order to redirect future resources into other pricing programs intended to incentivize increased order flow.

The Exchange also believes that its proposal is equitable and not unfairly discriminatory as the note 6 incentive will be eliminated for all Market Makers. Further, the Exchange notes that the proposed changes will not adversely impact any market participant's ability to otherwise qualify for reduced fees or rebates offered under other programs in the Pricing Schedule.

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. In terms of intra-market competition, the Exchange does not believe that its proposal will place any category of market participant at a competitive disadvantage. As discussed above, while parts of the Exchange's proposal provide more incentives for certain order flow and activity on the Exchange (*i.e.*, Market Maker liquidity adding activity and Priority Customer liquidity removing activity), the proposed changes are ultimately aimed at attracting greater liquidity to the Exchange, which benefits all market participants in the quality of order interaction.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards

applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act³⁷ and Rule 19b-4(f)(2)³⁸ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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 (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-MRX-2023-11 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-MRX-2023-11. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-MRX-2023-11 and should be submitted on or before July 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁹

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 2023-13895 Filed 6-29-23; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 12114]

Amendment of the Designations of ISIL-Libya and Real IRA (and Other Aliases) as Specially Designated Global Terrorists

Based upon a review of the administrative records assembled in this matter, and in consultation with the Attorney General and the Secretary of the Treasury, I have concluded that there is a sufficient factual basis to find that ISIL-Libya (and other aliases) uses

³⁷ 15 U.S.C. 78s(b)(3)(A)(ii).

³⁸ 17 CFR 240.19b-4(f)(2).

³⁹ 17 CFR 200.30-3(a)(12).

the additional alias Islamic State of Iraq and ash-Sham in Libya (also known as ISIS-Libya and ISIS-L) as its primary name; and that Real IRA uses the additional alias New Irish Republican Army (also known as New IRA, NIRA, and IRA Army Council) as its primary name.

Therefore, pursuant to section 1(a)(ii) of E.O. 13224, I hereby amend the designation of ISIL-Libya as a Specially Designated Global Terrorist to include the following new aliases: Islamic State of Iraq and ash-Sham in Libya, ISIS-Libya, ISIS-L; and amend the designation of Real IRA as a Specially Designated Global Terrorist to include the following new aliases: New Irish Republican Army, New IRA, NIRA, and IRA Army Council.

This notice shall be published in the **Federal Register**.

Dated: June 5, 2023.

Antony J. Blinken,
Secretary of State.

[FR Doc. 2023-13700 Filed 6-29-23; 8:45 am]

BILLING CODE 4710-AD-P

DEPARTMENT OF STATE

[Public Notice: 12113]

Review and Amendment of the Designations of ISIL-Libya and Real IRA (and Other Aliases) as Foreign Terrorist Organizations

Based upon a review of the Administrative Records assembled pursuant to section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) (“INA”), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designations of the aforementioned organizations as Foreign Terrorist Organizations have not changed in such a manner as to warrant revocation of the designations and that the national security of the United States does not warrant a revocation of the designations. I also conclude that there is a sufficient factual basis to find that ISIL-Libya (and other aliases) uses the additional alias Islamic State of Iraq and ash-Sham in Libya (also known as ISIS-Libya and ISIS-L); and that there is a sufficient factual basis to find that Real IRA (and other aliases) uses the additional alias New Irish Republican Army (also known as New IRA, NIRA, and IRA Army Council).

Therefore, I hereby determine that the designations of the aforementioned organizations as Foreign Terrorist Organizations, pursuant to section 219

of the INA (8 U.S.C. 1189), shall be maintained. Additionally, pursuant to section 219(b) of the INA, as amended (8 U.S.C. 1189(b)), I hereby amend the designation of ISIL-Libya (and other aliases) as a Foreign Terrorist Organization to include the following new aliases: Islamic State of Iraq and ash-Sham in Libya, ISIS-Libya, ISIS-L; and amend the designation of Real IRA (and other aliases) as a Foreign Terrorist Organization to include the following new aliases: New Irish Republican Army, New IRA, NIRA, and IRA Army Council.

This determination shall be published in the **Federal Register**.

Dated: June 5, 2023.

Antony J. Blinken,
Secretary of State.

[FR Doc. 2023-13699 Filed 6-29-23; 8:45 am]

BILLING CODE 4710-AD-P

SURFACE TRANSPORTATION BOARD

30-Day Notice of Intent To Seek Extension of Approval: Classification Index Survey Form

AGENCY: Surface Transportation Board.

ACTION: Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an existing collection without an OMB Control Number of a Classification Index Survey Form, as described below.

DATES: Comments on this information collection should be submitted by July 31, 2023.

ADDRESSES: Written comments should be identified as “Paperwork Reduction Act Comments, Surface Transportation Board, Classification Index Survey Form.” Written comments for the proposed information collection should be submitted via www.reginfo.gov/public/do/PRAMain. This information collection can be accessed by selecting “Currently under Review—Open for Public Comments” or by using the search function. As an alternative, written comments may be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Michael J. McManus, Surface Transportation Board Desk Officer: via email at oir_submission@omb.eop.gov; by fax at (202) 395-1743; or by mail to Room 10235, 725 17th Street NW, Washington, DC 20503.

Please also direct all comments to Chris Oehrle, PRA Officer, Surface Transportation Board, 395 E Street SW, Washington, DC 20423-0001, or to PRA@stb.gov. When submitting comments, please refer to “Paperwork Reduction Act Comments, Classification Index Survey Form.” For further information regarding this collection, contact Pedro Ramirez at (202) 245-0333 or pedro.ramirez@stb.gov. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION: The Board previously published a notice about this collection in the **Federal Register** (88 FR 26639 (May 1, 2023)). That notice allowed for a 60-day public review and comment period. No comments were received.

Comments are requested concerning: (1) the accuracy of the Board’s burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) 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, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board’s request for OMB approval.

Subjects: In this notice, the Board is requesting comments on the following information collection:

Description of Collection

Title: Classification Index Survey Form.

OMB Control Number: 2140-00XX.

Form Number: Classification Index Survey Form.

Type of Review: Existing Collection without an OMB Control Number.

Respondents: All railroad companies that are not required to file an Annual Report (Form R-1) and find that their classification has changed (*e.g.*, a change from Class III railroad, *i.e.*, a small railroad, to a Class II railroad, *i.e.*, a medium-sized railroad).

Number of Respondents: One per year.

Estimated Time per Response: Less than 24 hours. For any railroad changing classification, this estimate includes time spent reviewing instructions; searching existing data sources; gathering and maintaining the data needed; completing and reviewing the collection of information; and converting the data from the carrier’s

individual accounting system. (Generally, railroads will know whether they are close to changing among the three classifications.)

Frequency of Response: On occasion.

Total Annual Hour Burden: Less than 24 hours annually.

Total Annual "Non-Hour Burden"

Cost: The Classification Index Survey Form may be submitted electronically without non-hourly costs.

Needs and Uses: Railroads are classified by size into groups of large, medium, and small carriers. The Board must determine the classification of each rail carrier as a Class I, Class II, or Class III railroad. Railroads with a Class I classification (large railroads) must file Annual Reports (Form R-1) under 49 U.S.C. 11145. See OMB Control Number 2140-0009 (Class I Railroad Annual Reports). These reports are used by the Board, other Federal agencies, and industry groups to monitor and assess railroad industry growth, financial stability, traffic, and operations, and to identify industry changes that may affect national transportation policy. All other railroads (those not required to file an (R-1) Annual Report) shall annually compute their adjusted revenues using the "railroad revenue deflator formula," and, if the computation derived from that formula indicates a change in a carrier's classification, that carrier must submit a "Classification Index Survey Form" to the Board pursuant to 49 CFR part 1201 General Instructions 1-1 and § 1241.15.

Under the PRA, a Federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Section 3507(b) of the PRA requires, concurrent with an agency's submitting a collection to OMB for approval, a 30-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: June 26, 2023.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2023-13919 Filed 6-29-23; 8:45 am]

BILLING CODE 4915-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36709]

Naugatuck Railroad Company—Lease and Operation Exemption—Boston & Maine Corporation and Springfield Terminal Railway Company

Naugatuck Railroad Company (NAUG), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Boston & Maine Corporation (B&M) and acquire the right to operate from Springfield Terminal Railway Company (STR) as a common carrier over approximately 1,330 feet of rail line currently owned by B&M and operated by STR between a connection to the Torrington Branch at engineering station 0+00 and engineering station 13+30, all in New Haven County, Conn. (the Line).

According to the verified notice, NAUG has entered into a land and rail assets lease agreement with CSX Transportation, Inc. (CSXT), on behalf of B&M and STR, which are both subsidiaries of CSXT. The verified notice states that, upon consummation of the agreement, NAUG will lease and operate the Line. NAUG states that it currently operates over the Torrington Branch, an approximately 19.6-mile rail line that extends between NAUG milepost 0.0 in Waterbury, Conn., and NAUG milepost 19.6 in Torrington, Conn. See *Naugatuck R.R.—Operation Exemption—State of Conn.*, FD 32793 (STB served Jan. 25, 1996).

NAUG certifies that its projected annual freight revenues will not result in the creation of a Class I or Class II rail carrier and will not exceed \$5 million. NAUG also certifies that the agreement does not include an interchange commitment.

The transaction may be consummated on or after July 14, 2023, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than July 7, 2023 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36709, 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 NAUG's representative,

John R. Gamm, John R. Gamm LLC, 32 Dutton Place Way, Glastonbury, CT 06033.

According to NAUG, 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: June 26, 2023.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2023-13938 Filed 6-29-23; 8:45 am]

BILLING CODE 4915-01-P

TENNESSEE VALLEY AUTHORITY

Cheatham County Generation Site Environmental Impact Statement

AGENCY: Tennessee Valley Authority.

ACTION: Notice of Intent; extension of comment period.

SUMMARY: The Tennessee Valley Authority (TVA) is announcing a second extension of the public comment period on the Cheatham County Generation Site Notice of Intent to Prepare an Environmental Impact Statement. A Notice of Intent to prepare an EIS was published in the **Federal Register** on May 19, 2023, announcing a 30-day comment period closing on June 20, 2023. TVA extended the comment period by 7 days until June 27, 2023. TVA is now extending the public comment period to July 7, 2023.

DATES: The comment period for the Notice of Intent published May 19, 2023, at 88 FR 32267, is extended to July 7, 2023. Comments must be postmarked, emailed, or submitted online no later than July 7, 2023.

ADDRESSES: Comments can be submitted by one of the following methods:

1. *Online:* TVA's NEPA website: <http://www.tva.gov/nepa>. Follow the instructions for submitting comments electronically on the website.

2. *Email:* NEPA@tva.gov.

3. *Mail:* J. Taylor Johnson, NEPA Compliance Specialist, 1101 Market Street, BR 2C-C, Chattanooga, Tennessee 37402.

Before including your address, phone number, email address, or other personal identifying information in your comment, please note that any comments received, including names and addresses, will become part of the project administrative record and will be available for public inspection.

FOR FURTHER INFORMATION CONTACT: For general information about the project, please contact J. Taylor Johnson, NEPA Compliance Specialist, by mail at 1101 Market Street, BR 2C-C, Chattanooga, Tennessee 37402, by email at nepa@tva.gov, or by phone at 423-751-2732.

SUPPLEMENTARY INFORMATION: The Cheatham County Generation Site (CHG) would generate approximately 900 Megawatts (MW) and replace generation capacity for a portion of the Cumberland Fossil Plant (CUF) second unit retirement planned by the end of 2028. The CHG CTs would be composed of multiple natural gas-fired frame CTs and natural gas-fired and oil-fired (*i.e.*, dual-fuel) Aeroderivative CTs. CHG would provide flexible and dispatchable transmission grid support and facilitate the integration of renewable generation onto the TVA bulk transmission system, consistent with the 2019 Integrated Resource Plan. TVA is inviting public comment concerning the scope of the EIS, alternatives being considered, and environmental issues that should be addressed as a part of this EIS.

On May 19, 2023, TVA published a Notice of Intent to prepare an EIS to address the potential environmental impacts associated with the proposed construction and operation of a simple cycle Combustion Turbine (CT) plant and Battery Energy Storage System (BESS) on a parcel of TVA-owned land in Cheatham County, Tennessee. On June 20, 2023, TVA extended the public comment period to June 27, 2023 (88 FR 39903). On June 21, 2023, TVA held a public open house. Due to public interest and multiple requests, TVA is extending the public comment period until July 7, 2023. The extension will allow the public more time after the June 21st open house to provide their written comments. The TVA website listed above contains relevant information about the proposed project. TVA urges the public to review this information on the website prior to submitting comments.

Susan Jacks,

General Manager, Environmental Resource Compliance.

[FR Doc. 2023-13963 Filed 6-29-23; 8:45 am]

BILLING CODE 8120-08-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at the Dona Ana County International Jetport, Santa Teresa, New Mexico; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice; correction.

SUMMARY: The Federal Aviation Administration published a document in the **Federal Register** of March 20, 2023, concerning request for comments on specifications for the notice of intent to rule on request to release airport property at the Dona Ana County International Jetport, Santa Teresa, New Mexico. The document contained incorrect acreage in the supplementary information.

FOR FURTHER INFORMATION CONTACT: Ms. Heidi Higginbotham, Program Manager, Federal Aviation Administration, Louisiana/New Mexico Airports District Office, Telephone (817) 222-5144.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of March 20, 2023, in FR Doc. 2023-05548, on page 16709, in the second column, correct the **SUPPLEMENTARY INFORMATION** caption to read:

SUPPLEMENTARY INFORMATION:

The County of Dona Ana requests the release of 12.027 acres of land requested which consists of two parcels of vacant land with a combined land area. Parcel #1 contains 11.95 acres and is triangular. Parcel #2 contains 0.077-acres and is triangular. The land was acquired by Deed conveyed to the city from the United States of America Bureau of Land Management Section 23 of the Airport and Airway development Act of 1970. The land proposed for release will be swapped for 5.68 acres by Paseo Del Norte, LLC. The property to be released will ultimately be sold to Franklin Mountain for the development of a logistics park. The benefit to civil aviation has long-term impacts from the logistics park with plans to construct an air cargo handling facility.

D. Cameron Bryan,

Acting Director, Office of Airports, Southwest Region.

[FR Doc. 2023-13443 Filed 6-29-23; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2008-0355; FMCSA-2011-0089; FMCSA-2014-0382; FMCSA-2015-0323; FMCSA-2018-0057; FMCSA-2019-0028; FMCSA-2019-0029; FMCSA-2021-0025]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 10 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have “no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.” The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before July 31, 2023.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA-2008-0355, Docket No. FMCSA-2011-0089, Docket No. FMCSA-2014-0382, Docket No. FMCSA-2015-0323, Docket No. FMCSA-2018-0057, Docket No. FMCSA-2019-0028, Docket No. FMCSA-2019-0029, or Docket No. FMCSA-2021-0025 using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov/, insert the docket number (FMCSA-2008-0355, FMCSA-2011-0089, FMCSA-2014-0382, FMCSA-2015-0323, FMCSA-2018-0057, FMCSA-2019-0028, FMCSA-2019-0029, or FMCSA-2021-0025) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click on the “Comment” button. Follow the online instructions for submitting comments.

- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200

New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590–0001.

- **Hand Delivery:** West Building Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.

- **Fax:** (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the “Public Participation” portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, fmcamedical@dot.gov. Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2008–0355, Docket No. FMCSA–2011–0089, Docket No. FMCSA–2014–0382, Docket No. FMCSA–2015–0323, Docket No. FMCSA–2018–0057, Docket No. FMCSA–2019–0028, Docket No. FMCSA–2019–0029, or Docket No. FMCSA–2021–0025), 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–2008–0355, FMCSA–2011–0089, FMCSA–2014–0382, FMCSA–2015–0323, FMCSA–2018–0057, FMCSA–2019–0028, FMCSA–2019–0029, or FMCSA–2021–0025) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, click the “Comment” button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an

individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA–2008–0355, FMCSA–2011–0089, FMCSA–2014–0382, FMCSA–2015–0323, FMCSA–2018–0057, FMCSA–2019–0028, FMCSA–2019–0029, or FMCSA–2021–0025) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov. As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver’s medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person

is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria¹ to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

The 10 individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in § 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 10 applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The 10 drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. In addition, for commercial driver’s license (CDL) holders, the Commercial Driver’s License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver’s Licensing Agency. These

¹ These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy*: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

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 5, 2023, 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 epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Alan Finlayson (AL); and Stephen Harmon (WV).

The drivers were included in docket number FMCSA–2015–0323 or FMCSA–2019–0029. Their exemptions are applicable as of July 5, 2023 and will expire on July 5, 2025.

As of July 12, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Prince Austin, Jr. (OH)
Frank Cekovic (PA)
Martin Ford (MS)
David Johnston (MN)
Enrico Mucci (PA)
Charles Skelton (AL)
Kevin Wiggins (KY)

The drivers were included in docket number FMCSA–2008–0355, FMCSA–2011–0089, FMCSA–2014–0382, FMCSA–2018–0057, or FMCSA–2019–0028. Their exemptions are applicable as of July 12, 2023 and will expire on July 12, 2025.

As of July 30, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), Charles Anthony (ND) has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers.

The driver was included in docket number FMCSA–2021–0025. Their exemption is applicable as of July 30, 2023 and will expire on July 30, 2025.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must remain seizure-free and maintain a stable treatment during the

2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the 10 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–13984 Filed 6–29–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2023–0033]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 17 individuals from the requirement in the Federal Motor

Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have “no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.” The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on June 21, 2023. The exemptions expire on June 21, 2025.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, fmcsamedical@dot.gov. Office hours are 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–2023–0033) 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, without edit, including any personal information the commenter provides, to www.regulations.gov. As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

On May 16, 2023, FMCSA published a notice announcing receipt of applications from 17 individuals requesting an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) and requested comments from the public (88 FR 31302). The public comment period ended on June 15, 2023, 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)(8).

The physical qualification standard for drivers regarding epilepsy found in § 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria¹ to assist medical examiners (MEs) in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on the 2007 recommendations of the Agency's Medical Expert Panel. The Agency conducted an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical

information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the Commercial Driver's License Information System for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System. For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency. A summary of each applicant's seizure history was discussed in the May 16, 2023, **Federal Register** notice (88 FR 31302) and will not be repeated in this notice.

These 17 applicants have been seizure-free over a range of 33 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last 2 years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially.

The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds further that in each case exempting these applicants from the epilepsy and seizure disorder prohibition in § 391.41(b)(8) would likely achieve a level of safety equal to that existing without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: (1) each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5T; and (4) each driver must provide a copy of the annual

medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 17 exemption applications, FMCSA exempts the following drivers from the epilepsy and seizure disorder prohibition in § 391.41(b)(8), subject to the requirements cited above:

Gregory Alves (FL)
 Cadan Asterino (AZ)
 Kevin Atwood (MI)
 Jon Brandy (AR)
 Sean Duffy (NJ)
 Arlen Graff (MN)
 Cody Helmke (OH)
 Brian Law (CO)
 Thomas Lepley (PA)
 Daniel Lozier (OH)
 Kevin Moore (WA)
 Jeffrey Raddatz (IA)
 Sergio Soto (AZ)
 Caleb Stinson (MN)
 Anthony Whitt (TN)
 Stephen Wilson (PA)
 Jacob Woliver (CA)

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. 2023-13983 Filed 6-29-23; 8:45 am]

BILLING CODE 4910-EX-P

¹ These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2023–015]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Automated Vehicle Transparency and Engagement for Safe Testing (AV TEST) Initiative

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for approval for extension with modification of a currently approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. The information collection described in this document is for NHTSA's Automated Vehicle Transparency and Engagement for Safe Testing (AV TEST) Initiative, which involves the collection of voluntarily-submitted information from entities involved in the testing of vehicles equipped with automated driving systems (ADS) and from States and local authorities involved in the regulation of ADS testing. The purpose of this collection is to provide information to the public about ADS testing operations in the United States and applicable State and local laws, regulations, and guidelines. A **Federal Register** Notice with a 60-day comment period soliciting comments on the information collection was published on April 6, 2023 (83 FR 20608). NHTSA received 3 comment submission and a brief summary and NHTSA's response to those comments is provided in this document.

DATES: Comments must be submitted on or before July 31, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the 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.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Chris Wiacek, Office of Data Acquisition, (NSA–100), Room W53–478, 1200 New Jersey Avenue SE, Washington, DC 20590. Mr. Wiacek's telephone number is (202) 366–4801. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (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. In compliance with these requirements, this notice announces that the following information collection request will be submitted OMB.

A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on April 6, 2023.

Title: Automated Vehicle Transparency and Engagement for Safe Testing (AV TEST) Initiative.

OMB Control Number: 2127–0748.

Form Number: NHTSA Form 1586—AV TEST Tracker eForm; NHTSA Form 1587—AV TEST Onboarding Form.

Type of Request: Request for approval for extension with modification of a currently approved information collection.

Type of Review Requested: Regular.

Length of Approval Requested: Three years from the date of approval.

Summary of the Collection of Information: The U.S. Department of Transportation (DOT), National Highway Traffic Safety Administration (NHTSA) was established by Congress to save lives, prevent injuries, and reduce economic costs due to motor vehicle crashes through education, research, safety standards, and enforcement activity. DOT and NHTSA are fully committed to reaching an era of crash-free roadways through the deployment of innovative lifesaving technologies. The prevalence of automotive crashes in the United States underscores the urgency to develop and deploy lifesaving technologies that can dramatically decrease the number of fatalities and injuries on our Nation's roadways.

NHTSA believes that Automated Driving System (ADS) technology, including technology contemplating no human driver at all, has the potential to significantly improve roadway safety in

the United States. This technology remains substantially in development phases with companies across the United States performing varying levels of development, research, and testing relating to the performance of various aspects of ADS vehicle technologies. While much of these development operations occur in private facilities and closed-course test tracks, many stakeholders have progressed to conducting ADS vehicle testing on public roads or in public demonstrations. Moreover, to regulate such operations in their jurisdictions, many local authorities, such as States and cities, have passed laws governing ADS vehicle testing on public roads. These statutes, regulations, and ordinances vary, ranging from operational requirements to mandating the submission of periodic reports detailing ADS vehicle operation.

Description of the Need for the Information and Proposed Use of the Information: The AV TEST Initiative seeks to enhance public education and engagement with public ADS vehicle testing by coalescing information regarding respondents' various testing operations or requirements into a centralized resource. This information collection seeks voluntarily-provided information from entities performing ADS testing about their operations and information from local authorities about requirements or recommendations for such operations. NHTSA maintains a digital platform on its website¹ that collects information from respondents and makes the information about ADS operations and applicable State and local requirements and recommendations available to members of the public.

The program supports two main objectives. The first objective is to provide the public with access to geographic visualizations of testing at the national, State, and local levels. This information is displayed on a graphic of the United States, with projects overlaid on the geographic areas in which the testing project is taking place. By clicking on a testing location, members of the public see additional information about the operation and the ADS operator. Additional information may include basic information about the ADS operator, a brief statement about the entity, specific details of the testing activity, high-level (non-confidential) descriptions of the vehicles and technology, photos of the test vehicles, the dates on which testing occurs, frequency of vehicle operations, the

¹ <https://www.nhtsa.gov/automated-vehicle-test-tracking-tool>.

number of vehicles participating in the project, the specific streets or areas comprising the testing routes, information about safety drivers and their training, information about engagement with the community and/or local government, weblinks to the company's websites with brief introductory statements, and a link to the company's Voluntary Safety Self-Assessment (VSSA).²

The second objective is to provide members of the public with information collected from States and local authorities that regulate ADS operations. State and local authorities will be asked to provide weblinks for specific ADS-related topics, such as statutes, regulations, or guidelines for ADS operations, privacy-related issues, emergency response policies and training, or other activities that cultivate ADS testing. This program provides a central resource for the aforementioned information concerning ADS testing across the United States.

Affected Public: There are two information collection components to this request. The first affects entities engaged in testing of ADS vehicles, including original manufacturers of ADS vehicles and ADS vehicle equipment, and operators of ADS vehicles. The second affects local authorities regulating testing of ADS vehicles within their jurisdictions, including States, cities, counties, and other municipalities.

Estimated Number of Respondents: NHTSA anticipates that the Initiative could expand to include up to 35 State or local government respondents and 40 ADS developer, ADS vehicle manufacturer, or ADS operator respondents per year.

Frequency: Participation is completely voluntary, and each participant will choose its respective degree of involvement and the frequency of its submissions. Therefore, the frequency of a participant's response

may vary due to a variety of factors, such as the degree of the entity's participation in the initiative or the frequency with which each entity modifies its ADS testing operations or, in the case of local authorities, amends its regulations governing such operations.

Number of Responses: Participation is completely voluntary, and each participant will choose the number and frequency of its submissions. Therefore, the number of responses from a participant will vary due to a variety of factors, such as the degree of the entity's participation in the initiative or the frequency with which each entity modifies its ADS testing operations or, in the case of local authorities, amends its regulations governing such operations.

Estimated Total Annual Burden Hours: NHTSA estimates that the annual burden of participation will be approximately 48 hours for private industry respondents that include ADS operators, developers, or vehicle manufacturers. This total number of hours represents approximately four hours per month to perform data entry for testing projects (4 hours × 12 months = 48). Therefore, for the estimated 40 ADS operator participants, the total burden is estimated to be 1,920 hours per year (40 respondents × 48 hours).

NHTSA estimates that each State or local authority respondent would spend approximately 10 hours responding to this collection. Therefore, for the estimated 35 State or local authority participants, the total burden is estimated to be 350 hours per year.

The total burden for the entire information collection request is estimated to be 2,270 hours (1,920 hours + 350 hours). The total burden hours have been reduced from the original estimate of 2,520 when the agency first sought approval for this information collection because of the lower estimated participation. However, the

agency believes the annual hours per respondent has not changed.

The labor cost associated with this collection of information is derived by (1) applying the appropriate average hourly labor rate published by the Bureau of Labor Statistics, (2) dividing by either 0.705³ (70.5%), for private industry workers, or 0.619 (61.9%), for state and local government workers, to obtain the total cost of compensation, and (3) multiplying by the estimated burden hours for each respondent type.

Labor costs associated with original manufacturers of ADS Vehicles or ADS vehicle equipment and operators of ADS vehicles are estimated to be \$60.48 per hour for "Project Management Specialists," Occupation Code 13–1082, (\$42.64⁴ per hour ÷ 0.705). The labor cost per private industry respondent for each year for development and submission of information is estimated to be \$2,903.04 (\$60.48 × 48 hours). Therefore, the total annual labor cost for private industry to participate in the AV TEST Initiative is estimated to be \$116,121.60 (\$2,903.04 × 40 respondents).

Labor costs associated with local and regional authorities, such as states, counties, and cities are estimated to be \$66.79 per hour for "Legal Support Workers," Occupation Code 23–2099, (\$41.34⁵ per hour ÷ 0.619). The labor cost per regional authority respondent for each year for development and submission of information is estimated to be \$667.90 (\$66.79 × 10 hours). Therefore, the total annual labor cost for regional authorities to participate in the AV TEST Initiative is estimated to be \$23,376.50 (\$667.9 × 35 respondents).

The total annual labor costs for all respondents, private industry, and regional authorities together, are estimated to be \$139,499 (\$116,122 + \$23,377). See Table 1 below for a summary of estimated burden hours and estimated labor costs.

TABLE 1—SUMMARY OF ESTIMATED BURDEN HOURS AND ESTIMATED LABOR COSTS

Respondent type	Number of respondents	Annual hours per respondent	Labor cost per hour	Annual labor cost per respondent	Total estimated burden hours	Total annual labor costs
Original Manufacturer of ADS Vehicles or ADS Vehicle Equipment and Operators of ADS Vehicles	40	48	\$60.48	\$2,903.04	1,920	\$116,122
State or Local Authority	35	10	66.79	667.900	350	23,377

² Voluntary Self-Assessments are described in Automated Driving Systems 2.0: A Vision for Safety, available at https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/13069a-ads2.0_090617_v9a_tag.pdf. VSSAs are covered by the PRA Clearance with OMB Control Number 2127–0723.

³ See Table 1. Employer Costs for Employee Compensation by ownership (Sep. 2022), available

at <https://www.bls.gov/news.release/eccec.t01.htm> (accessed March 14, 2023).

⁴ See May 2021 National Industry-Specific Occupational Employment and Wage Estimates NAICS 336100—Motor Vehicle Manufacturing, available (accessed March 14, 2023).

⁵ See May 2021 National Occupational Employment and Wage Estimates by ownership Federal, state, and local government, including government-owned schools and hospitals and the U.S. Postal Service, available at <https://www.bls.gov/oes/current/999001.htm#23-0000> (accessed March 14, 2023).

TABLE 1—SUMMARY OF ESTIMATED BURDEN HOURS AND ESTIMATED LABOR COSTS—Continued

Respondent type	Number of respondents	Annual hours per respondent	Labor cost per hour	Annual labor cost per respondent	Total estimated burden hours	Total annual labor costs
Total All Respondents	75				2,270	139,499

NHTSA's estimate for the burden hours for participants remained the same from the April 6, 2023, notice.

Estimated Total Annual Burden Cost: NHTSA estimates that there will be no costs to respondents other than labor costs associated with burden hours.

Summary of Public Comments: On April 6, 2023, NHTSA published a notice in the **Federal Register** Notice with a 60-day comment period soliciting comments on the information collection (88 FR 20608). NHTSA received a total of 3 comment submission from organizations including, Alliance for Automotive Innovation (Auto Innovators), Owner-Operator Independent Drivers Association (OOIDA) and a joint submission from Safe Kids Worldwide and Safe Kids in Automated Vehicle Alliance (Safe Kids). A summary and response to the comments is provided below.

All commenters supported the Initiative's objective to enhance public education and engagement with public ADS vehicle testing by coalescing information regarding respondents' various testing operations or requirements into a centralized resource including information collected from States and local authorities that regulate ADS operations. Specifically, Auto Innovators commented that providing the public with access to see where testing is occurring at the national, state, and local levels helps provide additional transparency and assurances for how safety, mobility and accessibility issues are being addressed by innovators in the AV space, which is critical for building public acceptance of this burgeoning technology. OOIDA supported the objectives of the AV TEST Initiative by stating, it provides the public with direct and easy access to information about AV testing and development, along with information from states regarding activity, legislation, regulations, and local involvement in automation on our roadways. Safe Kids stated NHTSA's information and data collection under the AV TEST Initiative provides a mechanism to keep the public and safety advocates informed about automated vehicle testing activities to be conducted on public roads throughout the country.

The agency did not receive specific comments on the burden of the data collection, however OOIDA and Auto Innovators provided additional comments on how the agency may enhance the Initiative.

OOIDA stated the voluntary nature of AV TEST has not been effective in producing the necessary safety data to implement informed regulatory policies for autonomous vehicles. The AV TEST Initiative's voluntary structure prevents the program from best accomplishing its goals and NHTSA must require mandatory data transparency from manufacturers because it will help educate consumers, the industry, and regulators about the actual reliability and performance of autonomous technology.

In response, the agency's objective of the AV TEST Initiative is to provide members of the public with a centralized database of high-level information about ADS testing activities and State and local laws, recommendations, and initiatives. It is, therefore, outside of the scope of the project to make any reporting mandatory or to expand the collection to include safety information or information that NHTSA would use to evaluate the safety of ADS operations.

The Auto Innovators provided further comments specific to the AV TEST Initiative and how data is presented to the public. The Auto Innovators stated that it is important that NHTSA conduct periodic reviews to verify the accuracy of information that is made available on the AV TEST initiative portal, and that it is up to date. This may include spot check outreach to select organizations to provide updates on the status of their operations, or other updates to the data where the information is known to no longer be accurate (for example, if an AV tester were to cease operations).

In response, the agency agrees with the Auto Innovators and believes accurate data serves the intent of the Initiative to enhance public education and engagement with public ADS vehicles. However, NHTSA notes that data submitted as part of the AV TEST Initiative may become stale. For example, because the AV TEST Initiative is voluntary, an ADS operator could provide information on an ADS operation and never update NHTSA

when the operation is completed.

Although we provide a mechanism for participants to change the status of test sites from active to inactive or completed, participants may not update the status of an operation. NHTSA does reach out to program participants about operations that has not been updated for an extended period of time. In addition, we have provided participants the ability to remove out-of-date information and archive the data, which removes it from the AV TEST web page.

Furthermore, because the information submitted by participants is voluntary, before information is transferred to the public website the agency reviews the submissions for any obvious errors or concerns and will contact the participants accordingly prior to approval for publication if any concerns are identified. The agency also does a general periodic review for information that is out-of-date such as removing participants from the public website when we become aware the entity is no longer testing and has ceased operations.

The Auto Innovators also recommended NHTSA consider repurposing or rebranding the AV TEST initiative to emphasize not only the testing of AVs, but also to capture the transition from testing to real-world deployment. This is unlikely to create any additional burden in terms of the information provided as part of the AV TEST initiative but is likely an important distinction to make in building public acceptance and confidence in new technology. This could perhaps be achieved by using different colors and/or patterns to enable users to distinguish between testing and deployment in the online visualization tool.

In response, the agency believes the AV TEST Initiative needs to evolve over time as the technology progresses and the ADS developers transition their operations to have changing interaction with the public beyond testing and demonstration. Currently, the AV TEST Initiative provides participants the options to identify testing operations where the vehicles are providing a service to the public, however, currently specific to testing and not real-world deployment. As recently as May 10th, 2023, the agency held a workshop with

participants where we rolled out changes made to the AV TEST website based upon earlier feedback from participants to improve the conveyance of information to the public. We encourage participants and the public to contact the agency on ways to further improve the AV TEST experience.⁶ Prior to committing resources, the agency would like further information on the need and scope of the real-world deployment of ADS vehicles.

Lastly, Auto Innovators suggested, NHTSA should proactively encourage states to share information on statewide AV policies or initiatives as part of the AV TEST program, as this information is not only critical for public transparency, but also an important resource for manufacturers that need to develop systems to account for operational and policy related differences between regions.

In response, the agency has proactively reached out to states and encouraged them to participate in this voluntary program. In discussion with the states, the agency recognizes that each state has their own priorities with respect to ADS vehicles and may have limited resources or interest to participate in AV TEST. The agency continues to encourage state participation, however, as noted earlier this is a voluntary program.

NHTSA appreciates the commenters' input and will keep this input in mind when considering future approaches to ADS technologies.

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 agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including 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.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as

amended; 49 CFR 1.49; and DOT Order 1351.29.

Chou-Lin Chou,

Associate Administrator, National Center for Statistics and Analysis.

[FR Doc. 2023-13902 Filed 6-29-23; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT-OST-2023-0063]

Agency Information Collection Activities: Approval of Information Collection

AGENCY: Office of the Secretary (OST), DOT.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Department of Transportation (DOT) invites public comments on our intention to request Office of Management and Budget (OMB) approval for an information collection in accordance with the requirements of the Paperwork Reduction Act of 1995. The collection is necessary for administration of the Multimodal Project Discretionary Grants (MPDG). This includes three funding opportunities: the "National Infrastructure Project Assistance grants program (Mega)," the "Nationally Significant Multimodal Freight and Highways Projects grants program (INFRA)," and the "Rural Surface Transportation Grant program (Rural)". The MPDG provides Federal financial assistance for surface transportation infrastructure projects—including highway and bridge, intercity passenger rail, railway-highway grade and separation, wildlife crossing, public transportation, marine highway, and freight and multimodal projects, or groups of such projects, of national or regional significance, as well as to projects to improve and expand the surface transportation infrastructure in rural areas.

DATES: Written comments should be submitted by August 29, 2023.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov> and follow the online 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:** West Building Ground Floor, Room W-12-140 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

Instructions: To ensure proper docketing of your comment, please include the agency name and docket number [DOT-OST-2023-0063] at the beginning of your comments. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: For further information regarding this notice, please contact the Office of the Secretary via email at MPDGgrants@dot.gov, or call Paul Baumer at (202) 366-1092. A TDD is available for individuals who are deaf or hard of hearing at 202-366-3993.

SUPPLEMENTARY INFORMATION: New Collection. OMB number will be issued after the collection is approved.

Title: Multimodal Project Discretionary Grant (MPDG).

Form Numbers: None.

Type of Review: New Information Collection Request (ICR).

Background: The Office of the Secretary ("OST") within the Department of Transportation (DOT) provides financial assistance for surface transportation infrastructure projects—including to highway and bridge, intercity passenger rail, railway-highway grade and separation, wildlife crossing, public transportation, marine highway, and freight and multimodal projects, or groups of such projects, of national or regional significance, as well as to projects to improve and expand the surface transportation infrastructure in rural areas. Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021) (Bipartisan Infrastructure Law, or BIL) provided funds to the Department across three programs to invest in projects of national or regional significance—the National Infrastructure Project Assistance grants program, found under 49 U.S.C. 6701 ("Mega"), the Nationally Significant Multimodal Freight and Highways Projects grants program, found at 23 U.S.C. 117 (Infrastructure for Rebuilding America or "INFRA"), and the Rural Surface Transportation Grant program, found at 23 U.S.C. 173 ("Rural"). To help streamline the process for applicants, the Department has combined the applications for the Mega, INFRA, and Rural programs into the MPDG common application.

⁶ ADSInformationDesk@dot.gov.

The Nationally Significant Multimodal Freight and Highways Projects grants program (“INFRA”) (23 U.S.C. 117) was established in the Fixing American’s Surface Transportation Act of 2015 (“FAST ACT”), Public Law 114–94 sec. 1105, and continued in the Infrastructure Investment and Jobs Act, Public Law 117–58 (2021). OST is referring to these grants as “FASTLANE” or “INFRA” Discretionary Grants, depending on the year of award.

The Bipartisan Infrastructure Law established two new programs along with the reauthorization of INFRA. The Mega Program, known statutorily as the National Infrastructure Project Assistance program (49 U.S.C. 6701), will support large, complex projects that are difficult to fund by other means and likely to generate national or regional economic, mobility, or safety benefits. The Rural Surface Transportation Grant Program (23 U.S.C. 173) will support projects to improve and expand the surface transportation infrastructure in rural areas to increase connectivity, improve the safety and reliability of the movement of people and freight, and generate regional economic growth and improve quality of life.

The DOT combined these three programs into single Notice of Funding Opportunity (NOFO) to provide a more efficient application process for project sponsors. While they remain separate

programs for the purposes of award, the programs share many common characteristics. Because of these shared characteristics, it is possible for many projects to be eligible and considered for multiple programs using a single application.

This notice seeks comments on the proposed information collection, which will collect information necessary to support the ongoing oversight and administration of previous awards, the evaluation and selection of new applications, the funding agreement negotiation stage for new awards, and the evaluation of the programs.

The reporting requirements for the program is as follows:

To be considered to receive a MPDG grant, a project sponsor must submit an application to DOT containing a project narrative, as detailed in the NOFO. The project narrative should include the information necessary for the Department to determine that the project satisfies eligibility requirements as warranted by law.

After the award announcement the Department will send out a voluntary survey to all applicants and webinar participants to help evaluate the application process.

Following the announcement of a funding award, the recipient and DOT will negotiate and sign a funding agreement. In the agreement, the recipient must describe the project that

DOT agreed to fund, which is the project that was described in the MPDG application or a reduced-scope version of that project. The agreement also includes project schedule milestones, a budget, and project-related climate change and equity planning and policies.

During the project monitoring stage, grantees will submit reports on the financial condition of the project and the project’s progress. Grantees will submit progress and monitoring reports to the Government on a quarterly basis until completion of the project. The progress reports will include an SF–425, Federal Financial Report, and other information determined by the administering DOT Operating Administration. This information will be used to monitor grantees’ use of Federal funds, ensuring accountability and financial transparency in the MPDG programs.

For the purposes of estimating the information collection burden below for new applicants and awardees, the Department is assuming that for each year 2023–2025, the Department will review approximately 500 applications in Year 1, negotiate 45 funding agreements in Year 2, and begin quarterly project monitoring for 45 projects in Year 3. For a new applicant in 2023, their burden will be 100 hours in 2023, 6 hours in 2024, and 20 hours in 2025. See Table 1 below:

TABLE 1

Respondent	Year 1 (2023)		Year 2 (2024)		Year 3 (2025)		Total
	Hours	Frequency	Hours	Frequency	Hours	Frequency	
2023 Applicant (500)	100	1					50,000
2023 Survey (700)	0.5	1					350
2023 Awardee (45)			6	1			270
2023 Recipient (45)					5	4	900
2024 Applicant (500)			100	1			50,000
2024 Survey (700)	0.5	1					350
2024 Awardee (45)					6	1	270
2024 Recipient (45)							
2025 Applicant (500)					100	1	50,000
2025 Survey (700)	0.5	1					350
2025 Awardee (45)							
2025 Recipient (45)							

This Notice is separately estimating the information collection burden for projects awarded from 2016–2022. Approximately 60 of these projects are in the project monitoring phase in Year 1, while 47 projects are still negotiating funding agreements. In Year 2,

approximately 30 of these projects will begin project monitoring, while approximately 20 projects will cease reporting once their projects are completed. In Year 3, 10 projects will begin project monitoring while 20 projects will cease reporting. The

individual burden for a project awarded from 2016–2021 will depend on when they were selected, when they completed negotiation of their funding agreement, and when their project reaches completion. See Table 2 below:

TABLE 2

Respondent	Year 1			Year 2			Year 3			Total
	Number	Hrs	Freq	Number	Hrs	Freq	Number	Hrs	Freq	
2016–2022 Awardee	47	4	1	10	4	1	0	4	1	200
2016–2022 Recipient	70	5	4	77	5	4	64	5	4	3,800
2016–2022 Project Closed	0	0	0	20	0	0	43	0	0	

The Department's estimated burden for this information collection is the following:

For New Applications:

Expected Number of Respondents: Approximately 500 per year.

Frequency: Once.

Estimated Average Burden per Response: 100 hours for each new Application;

For Funding Agreements:

Expected Number of Respondents: Approximately 45 in Year 1, 2 and 3.

Frequency: Once.

Estimated Average Burden per Response: 6 hours for each new Funding Agreement.

For Project Monitoring:

Expected Number of Respondents: Approximately 47 in Year 1, 93 in Year 2, 130 in Year 3.

Frequency: Quarterly.

Estimated Average Burden per Response: 5 hours for each request for Quarterly Progress and Monitoring Report;

For Program Evaluation (Survey):

Expected Number of Respondents: Approximately 700 per year.

Frequency: Once.

Estimated Average Burden per Response: 0.5 hours for each application;

Estimated Total 3-year Burden on Respondents: 80,750 hours. (New Applicants [75,000 hrs], Survey [1,050 hrs] New Awardees/Recipients [700 hrs] + Prior Awardees/Recipients [4000 hrs]).

The following is detailed information and instructions regarding the specific reporting requirements for each report identified above:

Application Stage

To be considered to receive a MPDG grant, a project sponsor must submit an application to DOT containing a project narrative, as detailed in the NOFO. The project narrative should include the information necessary for the Department to determine that the project satisfies eligibility requirements.

Applications must be submitted through www.Grants.gov. Instructions for submitting applications can be found at <https://www.transportation.gov/>

grants/mpdg-how-apply. The application must include the Standard Form 424 (Application for Federal Assistance), Standard Form 424C (Budget Information for Construction Programs), cover page, and the Project Narrative.

The application should include a table of contents, maps, and graphics, as appropriate, to make the information easier to review. The Department recommends that the application be prepared with standard formatting preferences (*i.e.*, a single-spaced document, using a standard 12-point font such as Times New Roman, with 1-inch margins). The project narrative may not exceed 25 pages in length, excluding cover pages and table of contents. The only substantive portions that may exceed the 25-page limit are documents supporting assertions or conclusions made in the 25-page project narrative. If possible, website links to supporting documentation should be provided rather than copies of these supporting materials. If supporting documents are submitted, applicants should clearly identify within the project narrative the relevant portion of the project narrative that each supporting document supports. At the applicant's discretion, relevant materials provided previously to a modal administration in support of a different USDOT financial assistance program may be referenced and described as unchanged.

OST estimates that it takes approximately 100 person-hours to compile an application package for a MPDG application. Since OST expects to receive 500 applications per funding round, the total hours required are estimated to be 50,000 hours (100 hours × 500 applications = 50,000 hours) on a one-time basis, per funding round.

Program Evaluation Stage (Survey)

To understand the MPDG grant process from the applicant's point of view, OST plans to send out a survey after all award decisions have been made. This survey will go to all applicants, both successful and unsuccessful, as well as webinar participants that did not apply and will

take approximately .5 hours to complete.

Funding Agreement Stage

DOT enters a funding agreement with each recipient. In the agreement, the recipient describes the project that DOT agreed to fund, which is typically the project that was described in the MPDG application or a reduced-scope version of that project. The agreement also includes a project schedule, budget, and project related climate change and equity planning and policies.

OST estimates that it takes approximately 6 person-hours to respond to provide the information necessary for funding agreements. Based on previous rounds of MPDG awards, OST estimates that there will likely be 45 agreements negotiated per additional funding round. The total hours required are estimated to be 270 (6 hours × 45 agreements = 270 hours) on a one-time basis, per funding round.

Project Monitoring Stage

OST requires each recipient to submit quarterly reports during the project to ensure the proper and timely expenditure of Federal funds under the grant.

The requirements comply with 2 CFR part 200 and are restated in the funding agreement. During the project monitoring stage, the grantee will complete Quarterly Progress Reports to allow DOT to monitor the project budget and schedule.

OST estimates that it takes approximately 5 person-hours to develop and submit a quarterly progress report. OST expects approximately 45 projects to be awarded per funding round, while grants awarded in prior years will reach completion during the year and would no longer need to submit these reports. OST expects recipients and awardees from 2016–2021 will require 3800 hours to submit project monitoring reports while new recipients and awardees will require 900 hours from 2023–2025.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1:48.

Issued in Washington, DC, on June 26, 2023.

John Augustine,

Director of the Office of Infrastructure Finance and Innovation, Office of the Under Secretary for Transportation Policy.

[FR Doc. 2023–13939 Filed 6–29–23; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee; Correction

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting; correction.

SUMMARY: In the **Federal Register** that was originally published on June 22, 2023, the day for this meeting is being corrected to Monday, July 24, 2023, at 3:00 p.m. Eastern Time. All other meeting details remain unchanged. This meeting will be held via teleconference.

DATES: The meeting will be held Monday, July 24, 2023.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Monday, July 24, 2023, at 3:00 p.m. Eastern Time via teleconference. This meeting was previously announced in the **Federal Register** June 22, 2023 at 88 FR 40927. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1503, Washington, DC 20224 or contact us at the website: <http://www.improveirs.org>.

The agenda will include reports from the committees, and subcommittee discussions on priorities the TAP will focus on for the 2023 year. Public input is welcomed.

Dated: June 26, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–13898 Filed 6–29–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0020]

Agency Information Collection Activity: Designation of Beneficiary Government Life Insurance and Supplemental Designation of Beneficiary Government Life Insurance; Withdrawn

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice; withdrawal.

SUMMARY: On Tuesday, June 27, 2023, the Veterans Benefits Administration (VA), published a notice in the **Federal Register** announcing an opportunity for public comment on the proposed collection Designation of Beneficiary Government Life Insurance (VA Form 29–336) and Supplemental Designation of Beneficiary Government Life Insurance (VA Form 29–336a). This notice was published in error; therefore, this document corrects that error by withdrawing this FR notice, document number 2023–13529.

DATES: As of June 27, 2023, the FR notice published at 88 FR 122 on Tuesday, June 27, 2023, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs, Washington, DC 20006, (202) 266–4688 or email maribel.aponte@va.gov.

SUPPLEMENTARY INFORMATION: FR Doc. 2023–13529, published on Tuesday, June 27, 2023, is withdrawn by this notice.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–13911 Filed 6–29–23; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0020]

Agency Information Collection Activity: Designation of Beneficiary Government Life Insurance and Supplemental Designation of Beneficiary Government Life Insurance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 29, 2023.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to “OMB Control No. 2900–0020” in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email maribel.aponte@va.gov. Please refer to “OMB Control No. 2900–0020” in any correspondence.

SUPPLEMENTARY INFORMATION:

Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA’s functions, including whether the information will have practical utility; (2) the accuracy of VBA’s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Designation of Beneficiary Government Life Insurance VA Form 29–336 and Supplemental Designation of Beneficiary Government Life Insurance VA Form 29–336a.

OMB Control Number: 2900–0020.

Type of Review: Extension of a currently approved collection.

Abstract: These forms are used by the insured to designate beneficiaries and select an optional settlement to be used when the insurance matures by death.

The information is required to determine the claimant's eligibility to receive the proceeds. The information on the form is required by law, 38 U.S.C. 1917, 1949 and 1952.

Affected Public: Individuals and households.

Estimated Annual Burden: 13,917 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 83,500.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–13913 Filed 6–29–23; 8:45 am]

BILLING CODE 8320–01–P



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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1782–P]

RIN 0938–AV05

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2024. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also includes requests for information regarding potential changes to the low-volume payment adjustment under the ESRD PPS. In addition, this proposed rule would update requirements for the ESRD Quality Incentive Program and the ESRD Treatment Choices Model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 25, 2023.

ADDRESSES: In commenting, please refer to file code CMS–1782–P. 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 <https://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–1782–P, P.O. Box 8010, Baltimore, MD 21244–8010. 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–1782–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:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

Delia Houseal, (410) 786–2724, for issues related to the ESRD Quality Incentive Program (QIP). ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

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: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on [Regulations.gov](https://www.regulations.gov) public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the 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.

Current Procedural Terminology (CPT) Copyright Notice: Throughout this proposed rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

- I. Executive Summary
 - A. Purpose
 - B. Summary of the Major Provisions
 - C. Summary of Cost and Benefits
- II. Calendar Year (CY) 2024 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
 - A. Background
 - B. Provisions of the Proposed Rule
 - C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Proposals and Application for CY 2024 Payment
 - D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2024
 - E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products for CY 2024
- III. Calendar Year (CY) 2024 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)
 - A. Background
 - B. Proposed Annual Payment Rate Update for CY 2024
- IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
 - A. Background
 - B. Proposals To Update the Regulation Text for the ESRD QIP
 - C. Proposed Updates to Requirements Beginning With the PY 2026 ESRD QIP
 - D. Proposed Updates to the Requirements Beginning With the PY 2027 ESRD QIP
- V. End-Stage Renal Disease Treatment Choices (ETC) Model
 - A. Background
 - B. Summary of the Proposed Provisions to the ETC Model
- VI. Collection of Information Requirements
- VII. Response to Comments
- VIII. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Impact Analysis
 - D. Detailed Economic Analysis
 - E. Accounting Statement
 - F. Regulatory Flexibility Act Analysis (RFA)
 - G. Unfunded Mandates Reform Act Analysis (UMRA)
 - H. Federalism
- IX. Files Available to the Public

I. Executive Summary

A. Purpose

This proposed rule proposes updates to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model. Additionally, this proposed rule proposes policies that reflect our commitment to achieving equity in health care for our beneficiaries by supporting our ability to assess whether, and to what extent, our programs and

policies perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities. Our policy objectives include its commitment to advancing health equity, which stands as the first pillar of the CMS Strategic Plan,¹ and reflect the goals of the Biden-Harris Administration, as stated in Executive Order 13985.² We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.”³ In our CY 2023 ESRD PPS final rule, we noted that, when compared with all Medicare fee-for-service (FFS) beneficiaries, Medicare FFS beneficiaries receiving dialysis are disproportionately young, male, and African-American, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting (87 FR 67183). In this proposed rule, we continue to address health equity for beneficiaries with ESRD who are also members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, and racial and ethnic minorities. The term underserved communities refers to populations sharing a particular characteristic, including geographic communities that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.⁴ Specifically, in this proposed rule, we are requesting information regarding a potential payment adjustment for geographically isolated and rural ESRD facilities, proposing additional payment for the subgroup of Pediatric ESRD Patients (as defined in 42 CFR 413.171), and furthering our efforts to determine if payment to ESRD facilities treating patients with co-morbidities such as sickle cell anemia is aligned with

resource use by such ESRD facilities. Additionally, we are proposing to add three new measures to the ESRD QIP measure set that are aimed at promoting health equity for ESRD patients, including by enabling ESRD facilities to identify gaps experienced by their patient populations.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This proposed rule would update the ESRD PPS for CY 2024.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This proposed rule would update the AKI payment rate for CY 2024.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program establishes incentives

for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. This proposed rule proposes several updates for the ESRD QIP, including: a revision to the regulatory definition of “minimum total performance score” that more accurately captures how we calculate the median of national ESRD facility performance on reporting measures; the codification of our previously finalized measure selection, retention, and removal policies; updates that would begin with Payment Year (PY) 2026, including one new measure, modifications to two current measures, and the removal of two measures; and the addition of two new measures beginning with PY 2027.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center), and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures.

The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled “Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures” (85 FR 61114), referred to herein as the “Specialty Care Models final rule.” We revised and updated certain ETC Model policies in the CY 2022 ESRD PPS final rule (86 FR 61874), and the CY 2023 ESRD PPS final rule (87 FR 67136). In this rule, we are proposing to revise our regulations at 42 CFR 512.390 to acknowledge the availability of administrative review of targeted review requests. This change would provide ETC Participants with information about the availability of administrative review if an ETC Participant wishes to seek additional review of its targeted review request.

B. Summary of the Major Provisions

1. ESRD PPS

- *Proposed update to the ESRD PPS base rate for CY 2024:* The proposed CY 2024 ESRD PPS base rate is \$269.99, an increase from the CY 2023 ESRD PPS base rate of \$265.57. This proposed amount reflects the application of the proposed combined wage index and transitional pediatric ESRD add-on payment adjustment (TPEAPA) budget-neutrality adjustment factor (0.999652)

¹ Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: <https://www.cms.gov/pillar/health-equity>.

² 86 FR 7009 (January 25, 2021). <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>.

³ Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: <https://www.cms.gov/pillar/health-equity>.

⁴ 86 FR 7009 (January 25, 2021). <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>.

and a proposed productivity-adjusted market basket percentage increase of 1.7 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling \$269.99 $(\$265.57 \times 0.999652) \times 1.017 = \$269.99$).

- *Proposed annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2024, we are proposing to update the wage index values based on the latest available data.

- *Proposed annual update to the outlier policy:* We are proposing to update the outlier policy based on the most current data. Accordingly, we are proposing to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2024 using the latest available CY 2022 claims data. We are proposing to update the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2022 claims data, and update the FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021, and CY 2022. For pediatric beneficiaries, the proposed FDL amount would decrease from \$23.29 to \$13.71, and the proposed MAP amount would decrease from \$25.59 to \$24.53, as compared to CY 2023 values. For adult beneficiaries, the proposed FDL amount would increase from \$73.19 to \$78.21, and the proposed MAP amount would decrease from \$39.62 to \$38.58. The 1.0 percent target for outlier payments was not achieved in CY 2022. Outlier payments represented approximately 0.9 percent of total Medicare payments rather than 1.0 percent.

- *Proposed update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2024:* The proposed CY 2024 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is \$9.96. This offset amount would reflect the application of the proposed ESRD Bundled (ESRDB) market basket update of 1.7 percent $(\$9.79 \times 1.017 = \$9.96)$. There are no capital-related assets set to receive the TPNIES in CY 2024 for which this offset would apply.

- *Proposed clarifications to the TPNIES eligibility criteria:* We are proposing certain clarifications regarding our evaluation of the TPNIES eligibility criteria under § 413.236(b).

- *TPNIES application received for CY 2024:* This proposed rule presents a

summary of the one CY 2024 TPNIES application that we received by the February 1, 2023 deadline. This rule also presents our preliminary analysis of the applicant's claims related to substantial clinical improvement (SCI) and other eligibility criteria for the TPNIES.

- *Proposed modifications to the administrative process for the low-volume payment adjustment (LVPA):* We are proposing to create an exception to the current LVPA attestation process for ESRD facilities that are affected by disasters and other emergencies. This exception would allow ESRD facilities to close and reopen in response to a disaster or other emergency and still receive the LVPA. Additionally, it would allow an ESRD facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a disaster or emergency.

- *Proposed policy to measure patient-level utilization:* We are proposing to require ESRD facilities to report the time on machine (that is, the amount of time that a beneficiary spends receiving an in-center hemodialysis treatment) on claims. We are seeking comment on the proposed effective date of January 1, 2025, given the operational changes needed.

- *Proposed Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA):* We are proposing to establish and apply a new add-on payment adjustment of 30 percent of the per treatment payment amount to all renal dialysis services furnished to Pediatric ESRD Patients effective January 1, 2024, for CYs 2024, 2025, and 2026. This would serve to bring Medicare payments for renal dialysis services furnished to pediatric patients more in line with their estimated relative costs for the next three years until further collection and analysis of cost report data can be conducted.

- *Proposed add-on payment adjustment for after the end of the transitional drug add-on payment adjustment (TDAPA) period:* We are proposing a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period, which we would call the post-TDAPA payment adjustment. This payment adjustment would be case-mix adjusted and set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. The post-TDAPA payment adjustment would be applied to all ESRD PPS payments and paid for 3 years.

- *Proposed policy to require reporting of discarded billing units of certain renal dialysis drugs and biological products paid for under the ESRD PPS:*

We are proposing a new policy to require the use of the JW or JZ modifier on claims to track discarded amounts of single-vial and single-package renal dialysis drugs and biological products paid for under the ESRD PPS.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are proposing to update the AKI payment rate for CY 2024. The proposed CY 2024 payment rate is \$269.99, which is the same as the ESRD PPS base rate proposed for CY 2024.

3. ESRD QIP

We are proposing several updates for the ESRD QIP. We are proposing to codify the definition of "minimum total performance score" and to codify our previously finalized measure selection, retention, and removal policies. Beginning with PY 2026, we are proposing to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set, modify the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) reporting measure to align with updated measure specifications developed by the Centers for Disease Control and Prevention (CDC), remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure, and update the Clinical Depression Screening and Follow-Up measure's scoring methodology and convert that measure to a clinical measure. Beginning with PY 2027, we are proposing to add the Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set.

4. ETC Model

We are proposing to revise our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests.

C. Summary of Costs and Benefits

In section VIII.D.5 of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact table in section VIII.D.5.a of this proposed rule displays the estimated change in Medicare payments to ESRD facilities in CY 2024 compared

to estimated Medicare payments in CY 2023. The overall impact of the CY 2024 changes is projected to be a 1.6 percent increase in Medicare payments. Hospital-based ESRD facilities have an estimated 2.6 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 1.6 percent increase. We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$130 million in CY 2024 compared to CY 2023. This reflects a \$140 million increase from the proposed payment rate update, including approximately \$1.7 million in estimated TDAPA payment amounts, as further described in the next paragraph, as well as the proposed post-TDAPA payment amount. We estimate a \$10 million decrease from the proposed outlier payment update. Because of the projected 1.6 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 1.6 percent in CY 2024, which translates to approximately \$30 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products and § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies. The TDAPA and the TPNIES are not budget neutral.

As discussed in section II.D of this proposed rule, the TPNIES payment period for the Tablo® System ends on December 31, 2023. As discussed in section II.E of this proposed rule, the TDAPA payment period for KORSUVA™ (difelikefalin) would continue in CY 2024. We estimate that the overall TDAPA payment amounts in CY 2024 would be approximately \$1.7 million, of which, approximately \$345,000 would be attributed to beneficiary coinsurance amounts.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VIII.D.5.c of this proposed rule displays the estimated CY 2024 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2023. The overall impact of the CY 2024 changes

is projected to be a 1.6 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities would have an estimated 1.8 percent increase in Medicare payments compared with freestanding ESRD facilities that would have an estimated 1.6 percent increase. The overall impact reflects the effects of the proposed Medicare payment rate update and proposed CY 2024 wage index. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the proposed CY 2024 ESRD PPS base rate, would increase by \$1 million in CY 2024 compared to CY 2023.

3. Impacts of the Proposed Changes to the ESRD QIP

We estimate that the overall economic impact of the PY 2026 ESRD QIP would be approximately \$141.1 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The \$141.1 million estimate for PY 2026 includes \$121.1 million in costs associated with the collection of information requirements and approximately \$20 million in payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2027 ESRD QIP would be approximately \$148 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The \$148 million estimate for PY 2027 includes \$130.7 million in costs associated with the collection of information requirements and approximately \$17.3 million in payment reductions across all facilities.

4. Impacts of the Proposed Changes to the ETC Model

The impact estimate in section VIII.D.5.d of this proposed rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the changes in this proposed rule. We estimate that the ETC Model would result in \$28 million in net savings over the 6.5 year duration of the ETC Model. We also estimate that the changes proposed in this proposed rule would produce no change in net savings for the ETC Model. As the ETC Model targeted review process has already been finalized in the Specialty Care Models final rule and ETC Participants are not required to seek administrative review of targeted review determinations, we believe there would be minimal additional burden associated with our proposal.

II. Calendar Year (CY) 2024 End Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD

PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010, in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

We published a final rule, which appeared in the November 7, 2022, issue of the **Federal Register**, titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,” referred to herein as the “CY 2023 ESRD PPS final rule.” In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2023. We also finalized changes that included rebasing and revising the ESRDB market basket to reflect a 2020 base year, refining the methodology for outlier calculations, implementing a wage index floor of 0.600, implementing a permanent 5 percent cap on year-over-year wage index decreases for ESRD facilities, and modifying the definition of “oral-only drug.” For further detailed information

regarding these updates, see 87 FR 67136.

B. Provisions of the Proposed Rule

1. Proposed CY 2024 ESRD PPS Update

a. Proposed CY 2024 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

(1) Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

Although “market basket” technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term “ESRDB market basket,” as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the

quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

(2) Proposed CY 2024 ESRD Market Basket Update

We propose to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the proposed CY 2024 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.a.(2)(c), we are proposing to calculate the market basket update for CY 2024 based on the proposed market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(a) Proposed CY 2024 Market Basket Percentage Increase

Based on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket, the proposed CY 2024 market basket percentage increase is 2.0 percent. We also propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase in the final rule.

(b) Proposed Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the "productivity adjustment").

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. As

we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term "multifactor productivity" with "total factor productivity" (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.⁵ As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We referred readers to <https://www.bls.gov/productivity/> for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch>. In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we will be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Based on IGI's first quarter 2023 forecast, the proposed productivity adjustment for CY 2024 (the 10-year moving average of TFP for the period ending CY 2024) is 0.3 percentage point. Furthermore, we propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 productivity adjustment in the final rule.

(c) Proposed CY 2024 Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we propose to base the CY 2024 market basket percentage increase on IGI's first quarter 2023 forecast of the 2020-based ESRDB market basket. We propose to then reduce this percentage increase by the

estimated productivity adjustment for CY 2024 based on IGI's first quarter 2023 forecast. Therefore, the proposed CY 2024 ESRDB market basket update is equal to 1.7 percent (2.0 percent market basket percentage increase reduced by a 0.3 percentage point productivity adjustment). Furthermore, as noted previously, we propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase and productivity adjustment in the final rule.

We note that, as discussed in the CY 2023 ESRD PPS final rule (87 FR 67157), many commenters requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during the inflationary period occurring at that time, particularly accounting for what commenters stated was an error in the forecasted payment updates for CYs 2021 and 2022. In response to those comments, we reminded readers that ESRDB market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated, and forecasted data for the remainder. We explained that while there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase.⁶ We also explained that due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was -0.8 percentage point, while the CY 2021 ESRDB forecast error was +1.2 percentage point. At the time of the CY 2023 ESRD PPS final rule, CY 2022 historical data was not yet available to calculate a forecast error for CY 2022; however, based on the latest available historical data for CY 2022, we calculate that the CY 2022 ESRDB forecast error was +2.7 percentage point.

As we discussed in the CY 2023 ESRD PPS final rule (87 FR 67156), we recognized that recent higher inflationary trends impacted the outlook for price growth over the next several

⁵ Total Factor Productivity in Major Industries—2020. Available at: <https://www.bls.gov/news.release/prod5.nr0.htm>.

⁶ FAQ—Market Basket Definitions and General Information. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf>.

quarters. For that CY 2023 ESRD PPS final rule, we used an updated forecast of the price proxies underlying the market basket that incorporated more recent historical data and reflected a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. We explained that predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations, and that forecast error calculations are unpredictable (87 FR 67517). Historically, the positive differences between the actual and forecasted market basket increase in prior years have offset negative differences over time. Therefore, in accordance with our longstanding ESRDB market basket update methodology, we are not proposing to apply a forecast error adjustment to the ESRDB market basket update for CY 2024.

(d) Labor-Related Share

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. For the CY 2024 ESRD PPS payment update, we are proposing to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

b. Proposed CY 2024 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA

changes, including changes to CBSA numbers and titles. The bulletins are available online at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We applied the statewide urban average based on the average of all urban areas within the State to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we applied the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the US Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized a labor-related share of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18-04, beginning with the CY 2021 ESRD PPS wage index. In that same rule, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in

CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2024, as discussed in section II.B.1.a.(2)(d) of this proposed rule, the labor-related share to which the wage index would be applied is 55.2 percent.

(2) Proposed CY 2024 ESRD PPS Wage Index

For CY 2024, we propose to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We propose to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2024, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020 (Fiscal Year (FY) 2020 cost report data).

For CY 2024, we propose to update the ESRD PPS wage index to use the most recent hospital wage data. We propose that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the wage index), we would use such data, if appropriate, to determine the CY 2024 ESRD PPS wage index in the final rule. The proposed CY 2024 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>. Addendum A provides a crosswalk between the CY 2023 wage index and the proposed CY 2024 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>.

c. Proposed CY 2024 Update to the Outlier Policy

(1) Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services: (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.⁷

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and

medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.⁸ We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based on our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP amount per treatment plus the FDL amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term "national adjusted average" in this section of this proposed rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is,

the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments. In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We finalized that we would continue to follow our established methodology for the calculation of the adult and pediatric MAP amounts, but we would prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years.

(2) CY 2024 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2024, we are proposing to update the MAP amounts for adult and pediatric patients using the latest available CY 2022 claims data. We are proposing to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2022 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2020, CY 2021 and CY 2022, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). CY 2022 claims data showed outlier payments represented

⁷ Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

⁸ Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf>.

approximately 0.9 percent of total Medicare payments (87 FR 67172).

The impact of this proposed update is shown in Table 1, which compares the outlier services MAP amounts and FDL

amounts used for the outlier policy in CY 2023 with the updated proposed estimates for this proposed rule. The estimates for the proposed CY 2024 MAP amounts, which are included in

Column II of Table 1, were inflation adjusted to reflect projected 2024 prices for ESRD outlier services.

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TABLE 1: Outlier Policy: Impact of Proposal to Use Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2023 (based on 2021 data, price inflated to 2023)*		Column II Proposed outlier policy for CY 2024 (based on 2022 data, price inflated to 2024)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	\$24.13	\$41.36	\$23.52	\$40.26
Adjustments				
Standardization for outlier services	1.0819	0.9774	1.0645	0.9777
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$25.59	\$39.62	\$24.53	\$38.58
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$23.29	\$73.19	\$13.71	\$78.21
Patient-month-facilities qualifying for outlier payment	12.90%	5.90%	20.20%	5.10%

*Column I was obtained from Column II of Table 11 from the CY 2023 ESRD PPS final rule (87 FR 67176).

**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2020, 2021, and 2022.

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As demonstrated in Table 1, the estimated FDL per treatment that determines the CY 2024 outlier threshold amount for adults (Column II; \$78.21) is higher than that used for the CY 2023 outlier policy (Column I; \$73.19). The higher threshold is accompanied by a decrease in the adjusted average MAP for outlier services from \$39.62 to \$38.58. For pediatric patients, there is a decrease in the FDL amount from \$23.29 to \$13.71. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from \$25.59 to \$24.53.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2024 would be 5.10 percent for adult patients and 20.20 percent for pediatric patients, based on the 2022 claims data and methodology finalized in the CY 2023 ESRD PPS final rule. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services

(primarily reflecting lower use of ESAs and other injectable drugs).

(3) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1 percent targeted (87 FR 67170 through 67174). Based on the CY 2022 claims, outlier payments represented approximately 0.9 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. However, this is significantly closer to the 1 percent target than the outlier payments based on CY 2021 claims, which represented approximately 0.5 percent of total payments. We believe the update to the outlier MAP and FDL amounts for CY 2024 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us even closer to meeting our 1 percent outlier policy goal, because we would be using more current data for computing the MAP and FDL amounts, which is more reflective of current outlier services utilization rates. We also note that the proposed recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

d. Proposed Impacts to the CY 2024 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011

ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2024

We are proposing an ESRD PPS base rate for CY 2024 of \$269.99. This proposed update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2024, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2024 wage index budget-neutrality adjustment factor using treatment counts from the 2022 claims and facility-specific CY 2023 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2023. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2024. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2024 ESRD PPS wage index and proposed labor-related share for CY 2024. As discussed in section II.B.1.b of this proposed rule, the proposed ESRD PPS wage index for CY 2024 includes an update to the most recent hospital wage data and continued use of the 2018 OMB delineations. The total of these payments becomes the new CY 2024 amount of wage-adjusted expenditures for all ESRD facilities. The wage index

budget-neutrality factor is calculated as the target amount divided by the new CY 2024 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2024 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget-neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The proposed CY 2024 wage index budget-neutrality adjustment factor is 1.000120. This CY 2024 proposed wage index budget-neutrality adjustment factor reflects the impact of all wage index policy changes, including the proposed CY 2024 ESRD PPS wage index and labor-related share.

Proposed TPEAPA Budget-Neutrality Adjustment Factor: As explained in section II.B.1.g.(4) of this proposed rule, we are proposing a new, budget-neutral transitional add-on payment adjustment for pediatric ESRD renal dialysis services, which we would call the TPEAPA. The proposed CY 2024 budget-neutrality adjustment factor for the TPEAPA is 0.999532. The proposed methodology for deriving the budget-neutrality adjustment factor for the TPEAPA is discussed in detail in section II.B.1.g.(4).

Combined Wage Index and TPEAPA Budget-Neutrality Adjustment Factor: For purposes of calculating the ESRD PPS base rate for CY 2024, we are proposing to use one combined budget-neutrality adjustment factor that would include both the proposed wage index budget-neutrality adjustment factor and the proposed TPEAPA budget-neutrality adjustment factor. The proposed CY 2024 combined wage index and TPEAPA budget neutrality factor is $0.999652 (1.000120 \times 0.999532)$. This application would yield a proposed CY 2024 ESRD PPS base rate of \$265.48 prior to the application of the proposed CY 2024 market basket update percentage ($\$265.57 \times 0.999652 = \$265.48$).

Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase. As discussed previously in section II.B.1.a.(2)(a) of this proposed rule, the latest CY 2024 projection of the ESRDB market basket percentage increase is 2.0 percent. In CY 2024, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as

required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously in section II.B.1.a.(2)(b) of this proposed rule, the latest CY 2024 projection of the proposed productivity adjustment is 0.3 percentage point, thus yielding a proposed CY 2024 ESRD market basket update of 1.7 percent for CY 2024. Therefore, the proposed CY 2024 ESRD PPS base rate is $\$269.99 ((\$265.57 \times 0.999652) \times 1.017 = \$269.99)$.

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this proposed rule, we will refer to this as the "TPNIES offset amount."

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 calendar years.

There are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY 2024 as the TPNIES payment period for the Tablo® System ends on December 31, 2023, and the only TPNIES application for CY 2024 is not for a home dialysis machine. However, as required by § 413.236(f)(3)(v), we are proposing to update the TPNIES offset amount annually according to the methodology described above.

The proposed CY 2024 TPNIES offset amount for capital-related assets that are home dialysis machines is \$9.96. As

discussed previously in section II.B.1.a.(2)(c) of this proposed rule, the proposed CY 2024 ESRDB market basket update is 1.7 percent (2.0 percent ESRDB market basket percentage increase reduced by 0.3 percentage point productivity adjustment). Applying the proposed update factor of 1.017 to the CY 2023 TPNIES offset amount results in the proposed CY 2024 TPNIES offset amount of \$9.96 ($\$9.79 \times 1.017 = \$9.96$). We are proposing to update this calculation to use the most recent data available in the CY 2024 ESRD PPS final rule.

f. Proposed Refinement of the Low-Volume Payment Adjustment (LVPA)

(1) Background

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. Therefore, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility. In this section of the proposed rule, we discuss the low-volume payment adjustment (LVPA) under the ESRD PPS, request information from the public regarding the potential changes to LVPA methodology and potentially creating a new geographic-based payment adjustment in the future, and propose certain changes to the existing administrative process for the LVPA.

The current amount of the LVPA is 23.9 percent. In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume and to determine the treatment threshold for those ESRD facilities identified. After consideration of public comments, we established an 18.9 percent adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the base rate would encourage small ESRD facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of a low-volume facility under § 413.232(b) as part of the updated regression analysis and found that the ESRD facilities still had higher costs compared

to other ESRD facilities. A regression analysis of CYs 2012 and 2013 low-volume facility claims, and cost report data indicated a multiplier of 1.239 percent; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). In CY 2021, 366 ESRD facilities received the LVPA. Using the most recent available data for CY 2022, the number of ESRD facilities receiving the LVPA was 353.

(a) Current LVPA Methodology

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraph (g)(4)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. In order to receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, “treatments” mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis patients, one week of peritoneal dialysis is considered equivalent to three hemodialysis treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1 deadline for attestation submissions unless extraordinary circumstances justify an exception and specifies exceptions for certain years where the deadline is in December or January. The November 1st attestation

timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA payment for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a 23.9 percent increase is applied to the ESRD PPS base rate for all treatments furnished by the ESRD facility (80 FR 69001).

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID-19 Public Health Emergency (PHE). Under § 413.232(g)(4), for purposes of determining ESRD facilities’ eligibility for payment years 2021, 2022, and 2023, we will only consider total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. ESRD facilities that would not otherwise meet the number of treatments criterion because of the COVID-19 PHE may attest that their total dialysis treatments for those 6 months of their cost reporting period ending in 2020 are less than 2,000. The attestation must further include that although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID-19 PHE. MACs will annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2.

(b) Current Issues and Concerns From Interested Parties

Interested parties, including the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO),⁹ have recommended that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.¹⁰ These groups and other interested parties have also expressed concern that the strict treatment count introduces a “cliff-effect” that may incentivize ESRD facilities to restrict their patient caseload to remain below the 4,000 treatments per year for the LVPA threshold.¹¹

⁹ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.

¹⁰ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

¹¹ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

We considered several changes to the LVPA eligibility criteria to address the concerns that GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. Specifically, these interested parties have requested that we take into consideration the geographic isolation of an ESRD facility within the LVPA methodology. Section 1881(b)(14)(D)(iii) of the Act requires that the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. Our analysis has found that isolated low-volume facilities do not face higher costs than other low-volume facilities. Therefore, we do not believe that this requested change reconciles with the central statutory requirements and limitations for the LVPA, and we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act. Currently, we are analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, and facilities in rural areas, as set forth in 42 CFR 413.233. To avoid overlap with these existing facility-level adjustments, we are analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we are requesting information in section II.B.1.f.(2)(b) of this proposed rule.

In addition, we have heard from interested parties that the eligibility criteria for the LVPA are very explicit and leave little room for flexibility in certain circumstances (85 FR 71442). Some also view the attestation process as burdensome to ESRD facilities and believe it may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.¹² Given these concerns, we have considered alternative

approaches to the LVPA that would reduce burden, remove negative incentives that may result in gaming, and better target ESRD facilities that are critical for beneficiary access.

CMS's contractor has held three Technical Expert Panels (TEPs) to discuss potential refinements to the ESRD PPS.¹³ During the 2018, 2019, and 2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a request for information (RFI) to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural adjustment.¹⁴ One small dialysis organization within a large non-profit health system responded that it is reliant upon the LVPA and the rural adjustment and supports both adjustments, albeit with modifications. MedPAC renewed its support for a new Low-Volume and Isolated (LVI) adjustment with a three-tiered approach for treatment thresholds, which would incorporate geographic isolation into its methodology and may disincentivize gaming. MedPAC called upon CMS to provide clear and timely criteria for ESRD facility eligibility and ensure the LVPA methodology is transparent. In concurrence with MedPAC, a coalition of dialysis organizations, three large dialysis organizations (LDOs), a non-profit kidney organization, and a provider advocacy coalition commented that the rural adjustment should be eliminated and an LVI methodology should be adopted, as they considered a methodology based upon census tracts to be both complicated and lacking transparency. Numerous commenters wrote in support of a tiered adjustment to mitigate the cliff effect and gaming. Commenters raised concerns regarding the census tract methodology's reliance upon 'driving time' as a data measure, noting this presents legitimate equity issues. Those who have relied upon both the LVPA and rural payment adjustments to remain operational expressed opposition to elimination of either adjustment. The materials from

the TEPs and summary reports can be found at https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources. For this proposed rule, we considered the above-referenced input from interested parties and subsequent data obtained to inform the RFIs below.

(2) Requests for Information on Modification of LVPA Methodology and Development of a New Payment Adjustment Based on Geographic Isolation

As discussed in the previous section, we recognize the importance of revising the ESRD PPS LVPA adjustment methodology to ensure that payments accurately reflect differences in cost and adequately target low-volume facilities, and to strive for healthcare equity for ESRD beneficiaries. The LVPA and rural adjusters currently result in increased payments to some geographically isolated ESRD facilities, but these adjusters do not specifically target geographically isolated ESRD facilities. We noted several points of concern that interested parties have raised in the past, as well as certain statutory limitations that could apply to some of the methodological approaches suggested in the past. We are seeking information from the public about potential approaches to refine the ESRD PPS methodology, which we would take into consideration for any potential changes to the LVPA in the future.

This section addresses several RFIs regarding the LVPA and a potential new adjustment for geographically isolated ESRD facilities. Upon reviewing the RFIs, respondents are encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; RFIs do not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the United States (U.S.) Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted.

Please note that we will not respond to questions about the policy issues raised in these RFIs. We may or may not choose to contact individual responders. Such communications would only serve

¹² <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

¹³ https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.

¹⁴ <https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf>.

to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained because of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and will not be returned. We may publicly post the comments received, or a summary thereof.

(a) Comment Solicitation for Modifications to LVPA Methodology

We are soliciting comment on potential changes to the LVPA methodology, including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous

function. Any potential refinements to the LVPA methodology that may result from our consideration of these comments would be proposed through notice-and-comment rulemaking in the future. We request that commenters keep in mind that section 1881(b)(14)(D)(iii) of the Act requires the LVPA to reflect the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services.

(i) Maintain a Single LVPA Threshold

As discussions about modifying the existing treatment threshold or payment adjustment percentage have been ongoing since the beginning of the multi-year LVPA reform efforts, we are soliciting comments on maintaining a single threshold for the LVPA. ESRD facilities that fall below the treatment threshold would continue to receive payment, and payments would not be

adjusted for those ESRD facilities above the threshold. We are engaged in continuing monitoring efforts to align resource use with payment. If we were to re-compute the LVPA percentage amount using the latest available claims and cost report data and the methodology established in the CY 2011 and CY 2016 ESRD PPS final rules (75 FR 49118 through 49125 and 80 FR 69001), the current treatment threshold of 4,000 treatments per year would correspond to a 17.6 percent payment adjustment. The 4,000-treatment threshold could be maintained, or the treatment threshold could be recalibrated to maintain the 23.9 percent payment adjustment. Maintaining a single threshold would not address concerns regarding the potential for gaming or remove what commenters call the payment cliff. Potential approaches for a single LVPA threshold are outlined below in Table 2.

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TABLE 2: Potential Approaches for a Single LVPA Threshold

Option	Description
Status quo	4,000-treatment threshold with 23.9 percent payment adjuster
Maintain Treatment Threshold	4,000-treatment threshold with 17.6 percent payment adjuster
Maintain Payment Adjuster	Reduce treatment threshold to 3,750 treatments to maintain 23.9 percent payment adjuster

(ii) Establishment of Multiple LVPA Tiers

We are soliciting comment on creating a tiered payment adjustment that would include multiple thresholds, with separate payment adjustments calibrated so that ESRD facilities in tiers with the lowest treatment volume would receive the highest payment adjustment, and vice versa. MedPAC has previously recommended setting LVPA treatment thresholds at fewer than 4,000 treatments, between 4,000 and 4,999 treatments, and between 5,000 and 6,000 treatments, with payment adjustments calibrated so that ESRD facilities in tiers with the lowest volume would receive the highest

payment adjustment, and vice versa.¹⁵ Establishing multiple thresholds, with a separate payment adjustment for ESRD facilities under each threshold level, would reduce the potential for gaming through reduction of the magnitude of the payment cliff. Additionally, LVPA eligibility would be expanded to more ESRD facilities. We are soliciting comments regarding establishment of multiple thresholds, including up to an eight-tiered structure for the LVPA. Tables 3 through 6 outline various methodological options. Tables 3 through 4 would establish larger adjustment factors on average than the current methodology, but would require reductions to the ESRD PPS base rate to maintain budget neutrality. Tables 5

through 6 show adjustment factors which are scaled to maintain budget neutrality within the LVPA, keeping the LVPA's budget at the same amount that would occur under the current methodology without requiring reductions to the ESRD PPS base rate. As illustrated below, scaling the adjusters while maintaining budget neutrality within the LVPA results in lower LVPA adjusters. For example, Tier 1 (less than 5,000 treatments) in the Four-Tiered Model varies based on the approach to maintaining budget neutrality, as the LVPA adjuster is 13.7 percent where budget neutrality is maintained within the ESRD PPS (Table 3) and 5.8 percent where budget neutrality is maintained within the LVPA (Table 5). For comparison, the

¹⁵ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.

Eight-Tiered Model shows that for Tier 1 (less than 1,000 treatments), ESRD facilities would receive a 123 percent

LVPA adjuster where budget neutrality is maintained within the ESRD PPS (Table 4) and 40.5 percent LVPA

adjuster where budget neutrality is maintained within the LVPA (Table 6).

TABLE 3: LVPA Adjustment with Four Tiers (\$1.20 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	LVPA Adjusters
Tier 1 (less than 5,000)	13.7%
Tier 2 (5,000 – 5,999)	8.4%
Tier 3 (6,000 – 6,999)	4.7%
Tier 4 (7,000 – 7,999)	1.9%

TABLE 4: LVPA Adjustment with Eight Tiers (\$1.80 reduction to the ESRD PPS Base Rate to Maintain Budget Neutrality)

Tier (by treatment count)	LVPA Adjusters
Tier 1 (less than 1,000)	123.0%
Tier 2 (1,000- 1,999)	57.6%
Tier 3 (2,000-2,999)	33.9%
Tier 4 (3,000-3,999)	21.4%
Tier 5 (4,000 – 4,999)	13.7%
Tier 6 (5,000 – 5,999)	8.4%
Tier 7 (6,000 – 6,999)	4.7%
Tier 8 (7,000 – 7,999)	1.9%

TABLE 5: LVPA Adjustment with Four Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	LVPA Adjuster	Est. Facilities Receiving Adjustment
Tier 1 (less than 5,000)	5.8%	767
Tier 2 (5,000 – 5,999)	3.6%	331
Tier 3 (6,000 – 6,999)	2.0%	332
Tier 4 (7,000 – 7,999)	0.8%	318

TABLE 6: LVPA Adjustment with Eight Tiers (Adjusters scaled to maintain total LVPA payments at current levels)

Tier (by treatment count)	LVPA Adjuster	Est. Facilities Receiving Adjustment
Tier 1 (less than 1,000)	40.5%	22
Tier 2 (1,000- 1,999)	19.0%	69
Tier 3 (2,000-2,999)	11.2%	137
Tier 4 (3,000-3,999)	7.1%	250
Tier 5 (4,000 – 4,999)	4.5%	290
Tier 6 (5,000 – 5,999)	2.8%	331
Tier 7 (6,000 – 6,999)	1.5%	332
Tier 8 (7,000 – 7,999)	0.6%	318

BILLING CODE 4120-01-C**(iii) Continuous Function**

We are also soliciting comments on potentially establishing a continuous function to adjust LVPA payments. Under this approach, ESRD facilities with the lowest volume would receive the highest payment adjustment, and the payment adjustment would decrease continuously as volume increases. This could include calibration of the point at which the payment adjustment becomes zero to correspond with the existing 4,000 treatment upper bound, or establishment of a new upper bound based on a regression analysis. Establishment of a continuous function has the potential to significantly reduce the potential for gaming by eliminating payment cliffs entirely. Additionally, this would increase payment for ESRD facilities with the lowest volume, therefore better aligning payment with resource use. Furthermore, a continuous function would potentially expand LVPA eligibility to the most ESRD facilities.

CMS is considering several approaches to modifying the LVPA to address concerns about its incentive structure, treatment threshold, and administrative burden, as expressed by interested parties (including the GAO, MedPAC, and industry representatives). We are issuing this RFI to seek feedback on the suggested changes to the LVPA, as described above, and to solicit further input from interested parties to inform future modifications to the methodology used to determine the LVPA.

In particular, CMS seeks input and responses to the following considerations, requests and questions:

- Regarding concerns about a payment cliff in the existing LVPA, we are considering implementing payment tiers or a continuous adjustment, based on treatment volume, in place of the current single tiered adjustment.

- ++ Please comment on which payment structure would be more appropriate: single threshold as currently employed, tiered structure, or continuous function, and provide the reasoning behind your recommendation.

- ++ Please also comment on which option would be most effective in removing gaming incentives and which option would bring greater congruency between cost of providing renal dialysis services and payment.

- Using the alternative methodology described above, under a tiered or continuous payment adjustment, the treatment threshold for eligibility would be determined based on the median treatment count among all ESRD facilities (approximately eight thousand treatments per year). The resulting tiers and incremental payment adjustments between tiers could follow several different configurations.

- ++ What factors should be evaluated to best determine the treatment count threshold, as well as the tiering structure? Specifically, comment on the treatment volume beneath which per-treatment costs begin to increase.

- ++ Please enumerate any concerns you might have should the implementation of a tiered or continuous adjustment result in an expanded set of eligible ESRD facilities, and payment redistribution.

- Interested parties have voiced concern regarding the administrative burden involved in the current LVPA attestation process. As such, we are

considering potentially decreasing the number of years of attestation data needed to determine LVPA eligibility.

- ++ Please comment on the extent to which this change would alleviate burden, and if there are other administrative changes that could be made to simplify this process.

- ++ Please describe any anticipated effects of decreasing the amount of treatment volume data used to determine LVPA eligibility.

- ++ Please describe the ways that simplifying the attestation process could help ESRD facilities with fewer resources to promote health equity by improving their ability to serve vulnerable and underserved communities.

(b) Comment Solicitation on the Development of a New Payment Adjustment Based on Geographic Isolation

CMS is striving to promote health equity by ensuring that ESRD facilities, including both rural and low-volume facilities, are being paid equitably for serving populations that are currently underserved. We are therefore soliciting comments on potentially assisting geographically isolated ESRD facilities and promoting access in these areas, including labor force hiring and retention. We are considering establishing a new payment adjustment that accounts for isolation, rurality, and other geographical factors. We are also requesting information on geographic isolation to determine if ESRD facilities that are currently considered rural would benefit from a geographic isolation adjustment. The new geographically based payment adjustment may consider local dialysis

need (LDN), as explained later in this section, instead of basing payment strictly upon a rural designation, as set forth in §§ 413.233 and 413.231(b)(2). We considered changes to the eligibility criteria to address the concerns that GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are not located near other ESRD facilities that are necessary to protect access to care. As noted above, under section 1881(b)(14)(D)(iii) of the Act, the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. Our preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas *did not* have higher costs than low-volume ESRD facilities overall. Therefore, certain changes that interested parties have suggested would not comport with the statutory requirements and limitations for the LVPA. We are soliciting comments on potential methodologies for creating a separate payment adjustment that could potentially address GAO and MedPAC's concerns, relying upon the authority under section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate.

During the 2020 ESRD PPS TEP, panelists discussed the alternatives to the current LVPA set forth below.¹⁶ One methodology involved utilization of census tracts to identify geographic areas with low demand, which suggested increased beneficiary access by incentivizing dialysis organizations to continue operating ESRD facilities in otherwise non-viable locations. An advantage to this approach would be identifying geographical areas, specifically census tracts, with low demand for dialysis. The TEP participants discussed that the identification of low demand for dialysis would improve targeting to ESRD facilities that are in isolated areas that ESRD beneficiaries travel far to access. Additionally, this would incentivize ESRD facilities to locate in underserved areas that are isolated and rural, promoting access to care for these disadvantaged populations. This methodology aligns with the methodology presented in the TEPs and

in the CY 2022 ESRD PPS proposed rule (86 FR 36396 through 36399).

CMS's preliminary analysis has shown that models based on this local dialysis need (LDN) methodology would often result in the ESRD facilities receiving the LDN payment adjustment (that is, ESRD facilities in geographic areas with low LDN) being the only dialysis provider for a number of miles. Additionally, our analysis shows that ESRD facilities receiving the LDN payment adjustment often would be located in a census tract that intersects with areas designated as Health Professional Shortage Areas (HPSAs). The methodology would involve dividing the U.S. into geographic areas based on a reasonable assessment of ESRD beneficiaries' ability or willingness to travel. Regarding interested parties' concerns that previous measures for travel time relied upon beneficiaries' access to a private vehicle (which many beneficiaries may lack), in collaboration with our data contractor, CMS has performed additional analysis regarding the travel time metric to include realized travel time between ESRD facilities and population centers of census tracts, instead of ESRD facilities and patient address. Sensitivity checks have shown that the exact location of patients with ESRD is not essential for accurately determining the LDN of census tracts. Latent demand is then calculated by counting the number of beneficiaries with ESRD near each ESRD facility. "Near" is defined by driving time to ESRD facilities. Latent demand is calculated by multiplying the number of beneficiaries near an ESRD facility by average number of treatments for ESRD beneficiaries. The threshold is then applied by determining the threshold of adjusted latent demand. That is, those ESRD facilities, which fall below the threshold are eligible.

We are considering approaches to implementing an additional payment adjustment for ESRD facilities operating in areas with low LDN/demand. The purpose of this RFI is to seek feedback on the approach described above and to solicit information from interested parties to inform the approach taken to implement this adjustment. Any new payment adjustment of this nature would be proposed through future notice-and-comment rulemaking.

In particular, we seek responses to the following questions.

- What factors should be considered in formulating a payment adjustment for ESRD facilities in isolated geographical areas or areas for which there is a low need for renal dialysis services?

- What are the best ways to incentivize renal dialysis service provision in isolated geographic areas?

- Our analysis of the LDN methodology has shown that low LDN census tracts intersect with areas designated as HPSAs. What impact would a payment adjustment based on geographic isolation have on the ability of ESRD facilities in isolated areas to recruit and retain health care professionals?

- Please comment on the appropriateness of maintaining the rural facility adjustment under § 413.233, if we were to establish an LDN payment adjustment in conjunction with a modified LVPA.

- Please comment on the relationship between geographic isolation and cost. Please provide any data that could further inform CMS's understanding of the relationship between geographic isolation and cost for low volume facilities.

- Please comment on the appropriateness of utilizing driving time between current beneficiary address and treatment location as the appropriate metric for travel time.

- Are there ways in which the suggested methodology for this potential payment adjustment could fail in targeting isolated ESRD facilities, or ESRD facilities in areas with low LDN?

- Are there ways in which the determination of LDN might be subject to gaming?

- Would a payment adjustment for ESRD facilities in areas with low LDN improve health equity? Are there specific recommendations to change the LDN methodology described above to promote quality access to care for all ESRD beneficiaries?

- Please comment on the favorability of CMS's implementation of a new payment adjustment for ESRD facilities in areas with low LDN as described above.

- Are there any other considerations we should keep in mind when considering proposing a new payment adjustment based on an LDN methodology?

(3) Proposal for an Exception to the Current LVPA Attestation Process for Disasters and Other Emergencies

Under our current regulations at 42 CFR 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in § 413.232(g)(4)) preceding

¹⁶ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf>.

the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. When we first established these requirements in the CY 2011 ESRD PPS final rule, we explained that looking across data for three years provided us with a sufficient information to view consistency in business operations (79 FR 49123). In the CY 2019 ESRD PPS final rule (83 FR 56949) and the CY 2021 ESRD PPS proposed rule (85 FR 42165), we acknowledged commenters' concerns that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility during disasters or other emergency situations like the COVID-19 PHE. Commenters have emphasized that low-volume facilities rely on the LVPA, and that loss of the payment adjustment could result in beneficiary access issues.

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42165), the COVID-19 PHE caused ESRD facilities to have to shift patients among ESRD facilities in order to provide uninterrupted care to their Medicare ESRD population. In some cases, this patient shifting increased dialysis treatments at some low-volume ESRD facilities, putting the ESRD facility temporarily over the LVPA treatment threshold. This increase in dialysis treatments, resulting from the PHE, disqualified some ESRD facilities that would have otherwise received the LVPA of 23.9 percent per treatment. In the CY 2021 ESRD PPS final rule (85 FR 71485), we established a policy that ESRD facilities would be held harmless from increases in treatment counts due to temporary patient shifting because of the PHE. To be held harmless, ESRD facilities must follow the attestation process for the exception set forth in § 413.232(g)(4) and are expected to provide supporting documentation to the MACs upon request. Interested parties have expressed support for CMS's swift response to the COVID-19 PHE's impact on ESRD facilities, with an association of dialysis providers stating that holding harmless LVPA status for these ESRD facilities will better ensure that ESRD patients can continue to access the life-sustaining dialysis treatment they need, particularly in rural and underserved areas where low-volume facilities

heavily depend on the LVPA to remain open and provide treatment for patients.

We recognize there could be future circumstances, potentially similar to the circumstances of the COVID-19 PHE, in which it would be appropriate to provide flexibilities with respect to certain LVPA requirements. Commenters have previously expressed concerns about the strict attestation requirements for ESRD facilities to remain eligible for the LVPA, particularly when faced with a disaster or other emergency, such as a local or national emergency, natural disaster, catastrophic event, or public health emergency. We recognize that during disasters or other emergencies, low-volume facilities could be forced to close, or could experience increases in their treatment counts if they treat patients who are displaced from a nearby ESRD facility that is impacted by such an event. For example, in August of 2021, an ESRD facility in Louisiana sustained significant damage as a result of Hurricane Ida, which required the ESRD facility to close for repairs and temporarily stop furnishing renal dialysis services. The ESRD facility served a rural community and for over 10 years received the LVPA due to the low number of dialysis treatments it furnished each year. This ESRD facility sought recourse to maintain its eligibility for the LVPA when it resumed operations following the required repairs to the ESRD facility, however, recourse was unavailable due to the limitations set forth in 42 CFR 413.232(b). When we established the LVPA in the CY 2011 ESRD PPS final rule, we stated that we believed the LVPA should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic (75 FR 49118). Given that these requirements for low-volume facilities were created to protect access to care for the vulnerable patient population that these ESRD facilities serve, adding certain flexibilities during disasters or other emergencies would promote our commitment to ensuring access to care for ESRD patients.

(a) Proposed Changes to the LVPA

We are proposing to make two changes to the LVPA regulation at § 413.232 to allow for more administrative flexibilities during disasters or other emergencies. First, we are proposing to create a new exception to the attestation process for disasters and other emergencies. Second, we are proposing to establish a process that would allow low-volume facilities to close and reopen in response to a

disaster or other emergency and still receive the LVPA. CMS would assess whether a particular situation is a disaster or other emergency based on the totality of the circumstances that could result in disruption of or inability to furnish renal dialysis services at one or more ESRD facilities, thus affecting the ESRD facility's or facilities' ability to qualify for the LVPA. For purposes of this proposal, disasters or other emergencies would include, but not be limited to, the below examples:

- A public health emergency declared by the Secretary due to a significant outbreak of infectious disease or bioterrorist attacks.
- Natural disasters including winter storms, floods, tornados, hurricanes, wildfires, earthquakes, or any combination thereof.¹⁷
- Catastrophic events outside of an ESRD facility's control that disrupt operations and result in an ESRD facility's closure, for example, loss of operations or patient shifting due to a local emergency such as fire, floods, earthquakes, or tornadoes, or
- Other disaster or emergency conditions under which a waiver could be granted pursuant to section 1135 of the Act.

CMS believes these proposed policy changes could help displaced ESRD patients maintain access to renal dialysis services by preventing ESRD facilities from permanently closing due to the loss of their LVPA. It is important that ESRD facilities that are receiving the LVPA are able to maintain LVPA eligibility despite the impacts caused by a disaster or other emergency. The proposed policy could potentially protect other ESRD facilities that need to maintain the LVPA in order to remain open from potentially losing their LVPA by exceeding the treatment threshold because they accepted displaced patients. We do not want the fear of losing the LVPA due to increased treatments exceeding the threshold to disincentivize ESRD facilities from accepting patients from other ESRD facilities experiencing a disaster or other emergency. It is also important that ESRD facilities that are forced to close due to a disaster or other emergency are able to maintain their LVPA eligibility upon reopening to ensure continued access in areas that otherwise may lack sufficient ESRD facilities. The policy could also help those ESRD facilities affected by the disaster or other emergency potentially resume operations and avoid permanent closure if they would be allowed to receive the

¹⁷ <https://www.dhs.gov/natural-disasters>.

LVPA upon reopening despite the closure or disruption of operations.

(i) Proposed Exception to the LVPA Treatment Threshold for ESRD Facilities That Accept Patients From an ESRD Facility Affected by a Disaster or Other Emergency

We are proposing to create an exception to the LVPA treatment threshold requirements set forth in 42 CFR 413.232(b)(1) under a new provision in § 413.232(g)(5), which would allow an ESRD facility to receive the LVPA even if it exceeds the LVPA threshold if its treatment counts increase due to treating additional patients displaced by a disaster or other emergency. Qualification for the proposed exception would require an ESRD facility to absorb those displaced patients from an outside or adjacent ESRD facility that experienced a temporary closure or operational disruption (such as a water shut off). If an ESRD facility accepts the patients of the ESRD facility affected by the disaster or other emergency, causing that ESRD facility to meet or exceed the 4,000-treatment count for all dialysis patients, it would attest to its MAC that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility due to a disaster or other emergency. We are proposing to define temporary patient-shifting in the context of the LVPA in the ESRD PPS as providing renal dialysis services to one or more patient(s) at any time through the end of the calendar year following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to the displaced patient(s). The ESRD facility would be required to request this exception from CMS by writing to the ESRD Payment Mailbox *ESRDPAYMENT@cms.hhs.gov* no later than the annual attestation deadline of November 1st. CMS would review the exception request within 30 days to determine if the ESRD facility qualifies for the exception. If approved by CMS, the ESRD facility would be paid the LVPA for Medicare beneficiaries for up to the first 4,000 dialysis treatments in the payment year in which the temporary patient-shifting occurred. Under this proposed exception, the ESRD facility would be held harmless for meeting or exceeding the 4,000 dialysis treatment threshold during one or more cost reporting years within the 3-year lookback for LVPA eligibility as long as their 4,000 dialysis treatment threshold was exceeded as a result of temporary patient-shifting from

the ESRD facility that experienced the disaster or other emergency. If CMS does not approve the request, CMS would notify the ESRD facility and the MAC, and the ESRD facility would be disqualified from receiving the LVPA until it meets all the LVPA criteria (including the 3-year lookback). Under this proposal, the ESRD facility receiving this exception must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that previously treated those patients and closed or experienced an operational disruption due to a disaster or other emergency and must provide such documentation to CMS and the MAC upon request. The ESRD facility requesting this exception would have to repeat the process for requesting an exception for each cost reporting year in which its treatment volume meets or exceeds 4,000 due to temporary patient-shifting from the ESRD facility that experienced the disaster or other emergency. Additionally, the ESRD facility requesting this exception would have to follow the attestation process as described at § 413.232(e) for the two payment years following the last cost reporting year in which its treatment volume meets or exceeds 4,000 due to treating displaced patients from the ESRD facility that experienced the disaster or other emergency and attest that the ESRD facility meets the criterion established at § 413.232.

As an example: If a disaster occurs on June 1, 2024, which results in ESRD facility X's closure or operational disruption resulting in ESRD facility Y (an existing low-volume facility) treating additional patients from ESRD facility X that puts ESRD facility Y's total renal dialysis treatments for cost reporting year 2024 over the 4,000 treatment threshold, ESRD facility Y would be required to request an exception to § 413.232(b)(1) from CMS by November 1, 2024 in order to continue receiving the LVPA. Since ESRD facility Y began treating the displaced patients in CY 2024, the window for temporary patient shifting would extend until December 31, 2025. To be approved for the exception under the new provision in § 413.232(g)(5), CMS would determine that ESRD facility Y furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of ESRD facility X resulting from a disaster or other emergency. Should the exception be approved by CMS, ESRD facility Y would receive the LVPA for up to the

first 4,000 treatments it furnished in 2024. Additionally, ESRD facility Y would not be disqualified from receiving the LVPA for PY 2025 and PY 2026 due to exceeding the treatment volume threshold in cost reporting year 2024, assuming the temporary patient-shifting from ESRD facility X occurred only in cost reporting year 2024. For PY 2025 and PY 2026 ESRD facility Y would have to attest that it meets all the criterion for the LVPA because it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency and received an exception for cost reporting year 2024. This would be the same attestation process as if ESRD facility Y did not furnish any excess treatments and was attesting that it continued to meet the criteria for the LVPA for those payment years. If the closure or operational disruption of ESRD facility X causes the treatment volume for ESRD facility Y to meet or exceed the 4,000 dialysis treatment threshold in cost reporting year 2025, ESRD facility Y would have to submit another request for an exception by November 1, 2025. Should this exception be approved, ESRD facility Y would receive the LVPA for up to the first 4,000 treatments it furnished in cost reporting year 2025 and would not be disqualified from receiving the LVPA for payment year 2026 and payment year 2027 due to exceeding the treatment volume threshold in cost reporting year 2024 and cost reporting year 2025. If ESRD facility Y continued to treat displaced patients from ESRD facility X in cost reporting year CY 2026, it would only be considered temporary patient-shifting if ESRD facility Y treated those patients before January 1 2026, and if patients treated after January 1 2026 cause ESRD facility Y to exceed the 4,000-treatment volume threshold in cost reporting year 2026 then the ESRD facility would be disqualified from receiving the LVPA under § 413.232(b)(1). Under this example, ESRD facility Y would still have to meet the other eligibility requirements to receive the LVPA in any PY in which the ESRD facility would receive the LVPA.

(ii) Proposed Exception to the LVPA Closure Provision for ESRD Facilities Affected by a Disaster or Other Emergency

In addition to proposing an exception to the treatment threshold requirement under § 413.232(b)(1) and (g)(5), we are proposing an exception under

§ 413.232(g)(6) that would allow an ESRD facility to still receive the LVPA if it temporarily closes. That is, if an ESRD facility temporarily ceases to operate and the patients must go to another ESRD facility to receive renal dialysis services due to a disaster or other emergency, and the ESRD facility subsequently reopens, we are proposing to create an exception to the requirement in § 413.232(b)(2) that an ESRD facility “has not opened, closed, or received a new provider number” in the 3 cost reporting years preceding the payment year. If an ESRD facility is affected by a disaster or other emergency and the ESRD facility is forced to close and re-open later, the ESRD facility would need to request an exception from CMS in writing at the ESRD Payment Mailbox at ESRDPAYMENT@cms.hhs.gov within 60 days of the closure and inform the MAC of the request. CMS would review the request within 30 days of receipt and either approve the request based on a determination that the ESRD facility closed or experienced an operational disruption due to a disaster or other emergency, or deny the request, and would inform both the ESRD facility and the MAC of its decision.

Upon reopening and providing renal dialysis services, the ESRD facility would be required to notify CMS and the MAC in writing within 30 days of its reopening. CMS would acknowledge receipt of the written notification within 30 days. If the exception is approved and CMS is duly informed of the ESRD facility's reopening, the ESRD facility would remain eligible for the LVPA and the MAC would process payment accordingly. In order to continue receiving the LVPA the ESRD facility would still have to meet all the other eligibility requirements for the LVPA. The exception to § 413.232(b)(2) would be applicable for a period of 2 cost reporting years following the date of closure of the ESRD facility. After the 2 cost reporting year period the ESRD facility would follow the normal attestation process for the LVPA specified in paragraphs (e) and (g) of § 413.232. The ESRD facility would be required to maintain documentation regarding its closure, and to provide such supporting documentation to CMS and/or the MAC upon request.

For example, if a disaster occurs on June 1, 2024, which results in an ESRD facility experiencing a closure, the ESRD facility would request an exception to § 413.232(b)(2) from CMS within 60 days of June 1, 2024 (that is, on or before July 31, 2024). CMS would review the request and notify the ESRD facility and the MAC within 30 days if

the exception is approved or denied. If the ESRD facility then reopens on September 1, 2024, the ESRD facility would notify CMS and the MAC in writing within 30 days of reopening (that is, on or before October 1, 2024). CMS would notify the ESRD facility and the MAC of its receipt of the reopening notification within 30 days. If the exception was approved by CMS, the ESRD facility would remain eligible for the LVPA for the rest of payment year 2024 and for the entirety of payment year 2025 and payment year 2026, provided the ESRD facility continues to meet the other eligibility requirements for the LVPA.

(4) Proposed Technical Correction to 42 CFR 413.232(g)

We are proposing a technical correction at § 413.232(g) to replace “their” with “its,” to clarify the regulation language.

g. Proposed Transitional Pediatric ESRD Add-On Payment Adjustment for Pediatric Patients With ESRD Receiving Renal Dialysis Services

(1) Background

Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such payment adjustments as the Secretary determines appropriate, including a payment adjustment for pediatric providers of services and renal dialysis facilities. Determining such a payment adjustment has been historically difficult due to the consistent lack of data. The Medicare pediatric ESRD patient population receiving dialysis is small compared to the adult ESRD population, representing approximately 0.14 percent of the total ESRD patient population in 2022. In the past, CMS has considered various different payment adjustments for pediatric patients with ESRD, including different Medicare payments by sex or comorbidities (74 FR 49984 through 49986). However, many of these considered adjustments were not used as we were unable to get acceptable precision due to the small sample size of pediatric patients with ESRD.

Prior to the establishment of the ESRD PPS, payment for pediatric ESRD dialysis services was generally the same rate as adult ESRD dialysis, unless the ESRD facility qualified for an exception to the composite rate. Section 1881(b)(7) of the Act stated that, subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA), the Secretary shall provide for exceptions as may be warranted by unusual circumstances (including the

special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). During this time period, CMS received many comments and concerns regarding the payment rate for renal dialysis services furnished to pediatric patients with ESRD. Section 623(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) later amended section 422(a)(2) of BIPA to provide that any pediatric ESRD facility would be eligible for an exception to the composite rate, effective October 1, 2002. This statute defined pediatric ESRD facilities as facilities with at least 50 percent patients under the age of 18. This enabled pediatric ESRD facilities to obtain payments that specifically recognized the higher cost associated with treating these patients (69 FR 47530).

We finalized a basic case-mix adjustment to the composite payment rate in the CY 2005 Physician Fee Schedule (PFS) final rule published on November 15, 2004 (69 FR 66327). This included a 62 percent pediatric payment increase (that is, an adjustment factor of 1.62) applied to the composite payment rate per treatment for any facility when furnishing outpatient dialysis services to pediatric patients with ESRD. This factor was derived from the average exception amounts for 20 ESRD facilities that had received exceptions for pediatric patients. This was intended to be a temporary measure, which would be eliminated once we developed the case-mix methodology that would apply for the ESRD PPS bundled payment. The use of this methodology allowed CMS to provide additional payment for the pediatric ESRD population under the composite rate in a data-driven manner to account for the higher costs pediatric patients faced (69 FR 66327).

Section 153(b) of MIPPA added section 1881(b)(14) of the Act, which required CMS to implement an ESRD bundled PPS beginning January 1, 2011, under which a single payment for renal dialysis services is made in lieu of any other payment. Renal dialysis services generally include items and services included in the composite rate for renal dialysis services as of December 31, 2010 and services furnished to individuals for treatment of ESRD, which were formerly separately billable, including drugs and biological products and laboratory tests. In the CY 2011 ESRD PPS proposed rule, we proposed a single composite rate modifier of 1.199 for all Pediatric ESRD Patients receiving dialysis (74 FR 49982 through 49983). A “Pediatric ESRD Patient” is defined as an individual less than 18 years of age

who is receiving renal dialysis services. 42 CFR 413.171. We also proposed an eight-group system for separately billable renal dialysis services furnished to Pediatric ESRD Patients with two subdivisions for each of the following factors: age (under 13, 13 to 17), modality (hemodialysis, peritoneal dialysis) and number of comorbidities (none, one or more) (74 FR 49983 through 49987). The CY 2011 ESRD PPS proposed rule then calculated an “expanded bundle” modifier, which combined the composite rate and separately billable modifiers for each of the eight groups (74 FR 44987). These expanded bundle modifiers were the proposed pediatric patient-specific case-mix adjustment factors that would be

applied to the base rate under the ESRD PPS. These modifiers were based on a regression of costs for all renal dialysis services furnished to Pediatric ESRD Patients. Comments on this proposed rule indicated that many interested parties felt the expanded bundle modifier was insufficient (75 FR 49128). In the CY 2011 ESRD PPS final rule, we responded to those comments by implementing the first iteration of the current four-group system for both the expanded bundle and the separately billable services. This methodology was data driven, but unlike the simple regression for composite rate costs, allowed for different Medicare payment amounts based on two sets of two characteristics: age of the patient (under

13 or 13 to 17) and modality of the treatment (hemodialysis or peritoneal dialysis). Additionally, this methodology used the same groups for the expanded bundle and separately billable modifiers (75 FR 49134).

We codified the Pediatric ESRD Patient payment adjustment in § 413.235(b), which states that CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality. These multipliers were updated in the CY 2016 ESRD PPS final rule using the same methodology (80 FR 69001 through 69002). The current expanded bundle case mix adjusters are presented below in Table 7.

TABLE 7: Current Pediatric ESRDB Payment Modifiers

Current Pediatric ESRD Expanded Bundle Payment Modifiers by Age and Modality (effective 1/1/2016)		
Age	<13	13-17
Hemodialysis	1.306	1.327
Peritoneal Dialysis	1.063	1.102

Despite these changes intended to improve payment accuracy for renal dialysis services furnished to Pediatric ESRD Patients, we continue to receive comments and concerns from interested parties that the payment amounts for renal dialysis services furnished to Pediatric ESRD Patients are too low. In addition to comments received through the annual ESRD PPS rulemaking, we have also solicited comments from interested parties on several occasions. During the December 2020 TEP, we queried a panel of experts on how to improve payment for pediatric dialysis care under the ESRD PPS. Panelists¹⁸ generally preferred creating more refined case-mix adjusters over creating an entirely new pediatric ESRD PPS, citing the costs of creating an entirely new system both on CMS and the ESRD facilities and the need for new legislation to be able to increase payment through a separate pediatric ESRD PPS. Panelists also pointed to labor costs as a major reason for higher costs among pediatric dialysis clinics, because these patients need more nursing attention and specialized pediatric nutritionists.

In the CY 2023 ESRD PPS proposed rule (87 FR 38529), we issued a request for information regarding health equity

for pediatric patients with ESRD. Many commenters asserted that Medicare payments for Pediatric ESRD Patients are too low and that the ESRD PPS bundled payment does not target the unique issues facing ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

We are committed to improving health equity for Pediatric ESRD Patients receiving renal dialysis services by improving payment equity through more efficient Medicare payments. Ensuring Medicare payments are appropriate and reflect costs for renal dialysis services furnished to Pediatric ESRD Patients would allow more ESRD facilities to provide quality care to this vulnerable population. The main barrier to payment equity is the lack of sufficient data to determine the relative costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. To improve payment rate accuracy for Pediatric ESRD Patients, CMS has issued changes to the cost reports for both freestanding ESRD facilities and hospital-based ESRD facilities effective January 1, 2023.^{19 20 21}

¹⁹ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r7p242>.

²⁰ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i>.

²¹ 87 FR 26760 (May 5, 2022). [https://www.federalregister.gov/documents/2022/05/05/2022-09581/agency-information-collection-](https://www.federalregister.gov/documents/2022/05/05/2022-09581/agency-information-collection-activities-submission-for-omb-review-comment-request)

These changes include separate categories for labor and supplies used in furnishing renal dialysis services to Pediatric ESRD Patients. These updates are intended to provide data for CMS to more comprehensively estimate the additional costs associated with furnishing renal dialysis services to Pediatric ESRD Patients. However, we estimate it would take approximately 3 years to obtain and analyze the granular data provided by the stratified cost reports data from these changes that we need in order to consider proposing a more finely-tuned payment adjustment.

(2) Proposed Alternative Methodology for Estimating Relative Costs for Furnishing Renal Dialysis Services to Pediatric ESRD Patients

As noted previously, payment accuracy has been historically difficult for pediatric ESRD dialysis because of the small sample size of Pediatric ESRD Patients receiving renal dialysis services paid for under the ESRD PPS. Pediatric ESRD dialysis treatments are also furnished differently from adult ESRD dialysis treatments in several crucial ways. For example, pediatric ESRD facilities are more likely to be hospital-based and, on average, have lower treatment volume and are located in higher wage index areas. These

[activities-submission-for-omb-review-comment-request](https://www.federalregister.gov/documents/2022/05/05/2022-09581/agency-information-collection-activities-submission-for-omb-review-comment-request).

¹⁸ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

systematic differences in treatment, when combined with the small sample size, make it very difficult to obtain low variance estimates of the differences in costs between pediatric and adult ESRD dialysis patients. Even if simple cost models show statistically significant estimates, it is possible that the systematic differences between pediatric and adult ESRD facilities can bias these estimates. Obtaining a reliable estimate of the additional costs that Pediatric ESRD Patients incur would allow us to create a payment adjustment to bring relative Medicare payments more in line with relative costs.

One can account for this bias by selecting a specific sample of ESRD facilities that have similar characteristics except for proportion of dialysis treatments furnished to Pediatric ESRD Patients. This would help to show the additional costs of furnishing dialysis to Pediatric ESRD Patients based on the variation in costs

across the ESRD facilities. To achieve this, we would use propensity score matching (PSM).

PSM is a technique that uses regression analysis to account for systematic differences between two populations to isolate the effects of a single variable, in this case percentage of Pediatric ESRD Patients. The PSM regression includes a wide range of ESRD facility-level characteristics including facility type, size, geographic location, and the pediatric ESRD dialysis population nearby the ESRD facility in order to make a propensity score. This propensity score represents the probability that a given ESRD facility treats a high volume of Pediatric ESRD Patients given its facility-level characteristics.

Once the propensity score for each ESRD facility is determined, each ESRD facility with a significant percentage of Pediatric ESRD Patients (high-pediatric) is matched with the ESRD facility

without a significant percentage of Pediatric ESRD Patients (low-pediatric) with the most similar propensity score. We can then compare the relative per-treatment costs of those ESRD facilities to estimate the additional costs an ESRD facility faces when it furnishes renal dialysis services to a higher proportion of Pediatric ESRD Patients, controlling for some important facility-level characteristics. The dependent variable of this regression is the log of the cost per treatment for the ESRD facility. The independent variables are the percent of dialysis treatments that are furnished to Pediatric ESRD Patients, the log of the facility size, the type of ESRD facility (hospital based, children's hospital based or freestanding), the log of the wage index for the ESRD facility and the year for the cost report data. The regression equation for cost per treatment given a certain percentage of dialysis treatments furnished to Pediatric ESRD Patients is:

$$\text{Log}\left(\frac{\text{Cost}}{\text{Treatment}}\right) = \text{Pediatric Share} + \log(\text{Facility Size}) + \text{Hospital Type} + \log(\text{wage Index}) + \text{Year Indicator}$$

This cost regression should be unbiased due to the use of PSM. However, PSM also requires a reduction in sample size, because there are relatively few ESRD facilities with a significant number of treatments furnished to Pediatric ESRD Patients that could be matched using PSM. This smaller sample size inherently results in an increase in margin of error. We believe this is a necessary tradeoff because a biased estimate cannot be relied upon, but we must be cautious while using high-error estimates. The final result of this regression is that ESRD facilities that solely serve Pediatric ESRD Patients incur costs that are 40 percent higher per patient for furnishing renal dialysis services than similar ESRD facilities that serve no Pediatric ESRD Patients. The confidence interval of this estimate is 20 percent to 60 percent. Therefore, on average, furnishing renal dialysis services to a Pediatric ESRD Patient costs 40 percent more than furnishing renal dialysis services to an adult patient with ESRD.

(3) Current Medicare Payments for Renal Dialysis Services Furnished to Pediatric ESRD Patients

The ESRD PPS already accounts for some of the higher costs that ESRD facilities incur while furnishing renal dialysis services to Pediatric ESRD Patients through the case-mix adjusters. Because the analysis described above uses cost report data, it does not

incorporate either the current case-mix adjusters or payment rates for Pediatric ESRD Patients receiving renal dialysis services. Our most recent estimates show that payments for dialysis treatments furnished to Pediatric ESRD Patients were approximately 10 percent higher than for adult patients with ESRD in CY 2022.

We are striving for payment accuracy, which is achieved when relative Medicare payments are proportional to relative costs. There are several ways we could adjust ESRD PPS payments to achieve payment accuracy, including calculating the unaccounted-for cost differential, which is the amount by which ESRD PPS payments for pediatric ESRD renal dialysis services must be increased to achieve payment accuracy. We could do this by reducing the cost differential estimate of 40 percent by a factor 1.1 to account for the current payment differential of 10 percent. This would yield an unaccounted-for cost differential of approximately 30 percent (1.4 divided by 1.1 is 1.27 which we are rounding to 1.3). This is a reasonable estimate of the additional labor and supply costs, which are not accounted for by the current case-mix adjusters, incurred by ESRD facilities furnishing renal dialysis services to Pediatric ESRD Patients.

(4) Proposed Transitional Pediatric ESRD Add-On Payment Adjustment

Despite the high margin of error of the cost regression using PSM, we believe that 30 percent cost is the most reasonable estimate of the unaccounted-for costs incurred in treating Pediatric ESRD Patients compared to adult ESRD patients. Creating a new add-on payment adjustment using this figure would provide pediatric ESRD facilities with Medicare payments proportional to their estimated costs for a temporary period while we collect additional data. However, due to the high margin of error of the model, increasing Medicare payments to ESRD facilities such that payments are 40 percent higher for Pediatric ESRD Patients compared to all patients would risk making payments higher than appropriate. When we conduct the analysis with the more comprehensive cost report data provided by the cost report changes implemented for CY 2023, we might find that our analysis overestimated the cost of furnishing renal dialysis services to Pediatric ESRD Patients (that is, that the additional 30 percent payment adjustment was too large). If we finalize this transitional add-on payment adjustment for Pediatric ESRD Patients as proposed, pediatric ESRD facilities should be prepared for the possibility that the payment rate for Pediatric ESRD Patients could decrease in the future, should that be indicated by future data

analysis and finalized through notice-and-comment rulemaking. One alternative would be for CMS to propose a smaller, more cautious add-on payment adjustment based on the 20 percent lower bound of the confidence interval, leading to an additional 10 percent transitional add-on payment adjustment after accounting for the current payment rate. This option would still represent a significant increase in Medicare payments to ESRD facilities for Pediatric ESRD Patients without much risk of making payments higher than appropriate. However, this alternative option may lead to underpayment to ESRD facilities serving Pediatric ESRD Patients, which is contrary to our goal of aligning resource

use with payment. We are seeking comment on the most appropriate amount for the proposed transitional add-on payment adjustment.

We are proposing a new transitional add-on payment adjustment of 30 percent (adjustment factor of 1.3) for dialysis treatments furnished to Pediatric ESRD Patients for 3 calendar years, effective January 1, 2024. Based on the time lag for cost report data, 3 years should allow for enough time for CMS to get more detailed data from the changes to the cost reports described above. After that period, we would evaluate the more comprehensive cost report data from the first year of cost reporting periods beginning on or after January 1, 2023, to refine our methodology for determining the

payment rate for pediatric ESRD dialysis. As proposed, this would be a separate, additional add-on payment adjustment of 30 percent of the per treatment payment amount under \$413.230, which reflects the other patient and facility level adjustments. This adjustment would not be part of the case-mix adjusters. This payment adjustment would only apply to the ESRD bundled payment and not to any outlier adjustments. Due to the multiplicative nature of the case-mix adjusters it would function similarly to a 30 percent increase to the expanded bundle case-mix adjusters. For the purpose of comparison, the effective case-mix adjusters are presented below in Table 8.

TABLE 8: Pediatric ESRDB Effective Payment Modifiers

Pediatric ESRDB Effective Payment Modifiers by Age and Modality				
Age	Modality	Current Case- Mix Adjuster (Effective 1/1/2016)	Proposed 30% Increase Effective Case- Mix Adjusters	Alternative Proposed 10% Increase Effective Case- Mix Adjusters
<13	PD	1.063	1.382	1.169
<13	HD	1.306	1.698	1.437
13-17	PD	1.102	1.433	1.212
13-17	HD	1.327	1.725	1.460

The exact magnitude of the increase in payment would vary based on the age of the patient and the wage index of a given area; we estimate approximately \$80 for (hemodialysis-equivalent) peritoneal dialysis treatments and \$100 for hemodialysis treatments. This would represent a substantial increase in payment for renal dialysis services furnished to Pediatric ESRD Patients, and would account for the extra costs that this population incurs temporarily until additional cost data is available. This payment adjustment would apply for all dialysis treatments furnished to ESRD patients under the age of 18, not solely treatments furnished in pediatric ESRD facilities. This is warranted because many of the additional costs related to the treatment of Pediatric ESRD Patients are not specific to treatments furnished in pediatric ESRD facilities.

We are proposing to call this the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) and make this adjustment budget neutral. In general, add-on payment adjustments under section 1881(b)(14)(D)(iv) of the Act are not statutorily required to be

budget neutral under the ESRD PPS, but we believe in this instance that budget neutrality is appropriate, due to the manner in which this adjustment is derived. Other non-budget neutral add-on payment adjustments that we have established under this authority generally account for costs that were not used for the construction of the ESRD PPS bundled payment, such as the TDAPA for calcimimetics (80 FR 69013 through 69027). We have also established certain non-budget neutral add-on payment adjustments for items or services that were not commonplace, and therefore not adequately represented in cost reports, such as home dialysis training (75 FR 49063). However, we have implemented other payment adjustments under this authority in a budget neutral manner; for example, the changes to the wage index in the CY 2023 ESRD PPS final rule were implemented in a budget neutral manner as they represented a shifting of cost allocations, rather than new costs not originally included in the ESRD PPS bundled payment (87 FR 67157). This proposed TPEAPA is primarily for costs that would have been

included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule. As explained above, the methodology used both in that analysis, and when updating the case-mix adjusters, attributed pediatric ESRD renal dialysis services costs to the general population. Therefore, we believe it would be appropriate to reduce the ESRD PPS base rate to account for the new allocation of costs. Furthermore, any changes to the case-mix adjustments are required by section 1881(b)(14)(A)(ii) of the Act to be budget neutral, which means that any future modifications to the pediatric case-mix adjusters would be budget neutral. The budget neutrality adjustment factor for this proposed TPEAPA consisting of 30 percent of the per treatment payment amount would be 0.999532. Applying this budget neutrality factor to the ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated \$0.12. Under the alternative proposed 10 percent TPEAPA discussed previously in this section of the proposed rule, the budget neutrality factor adjustment would be 0.999847. Applying this

budget neutrality factor to the ESRD PPS base rate would reduce the ESRD PPS base rate by an estimated \$0.04.

To establish this new TPEAPA, we are proposing to amend § 413.235 by splitting current paragraph (b) into paragraphs (b)(1) and (2). Paragraph (b)(1) would set forth the established age and modality of treatment case mix adjustment methodology as currently stated in paragraph (b). Paragraph (b)(2) would state that beginning January 1, 2024, we would provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026. We are also proposing to revise the current language of § 413.235(b) to use the term “Pediatric ESRD Patients,” which is defined at § 413.171, to improve clarity for this section.

(5) Costs and Benefits for a Proposed Transitional Pediatric ESRD Add-On Payment Adjustment (TPEAPA)

We believe that CMS could better align the resource use of pediatric ESRD renal dialysis services with payment. Our analysis using the methodology outlined above has found that Pediatric ESRD Patients receiving renal dialysis services have an estimated 40 percent higher costs than adult patients and that the current payment adjusters account for 10 percent higher costs. Implementing a transitional 30 percent add-on payment adjustment for renal dialysis services furnished to Pediatric ESRD Patients would improve payment equity for these patients by increasing payments to more closely align with the estimated costs of treatment. A 30 percent increase in ESRD PPS payments for pediatric ESRD renal dialysis services would represent approximately \$80 to \$100 per pediatric ESRD dialysis treatment, although the exact magnitude of the increase would depend on age, modality and the wage index of the area. This payment increase would have beneficial health equity impacts on this population by improving access to care and quality of care. Some ESRD facilities may not be able to absorb the additional expense of the Pediatric ESRD Patient population. Patients may need to travel to a limited number of primarily hospital-based ESRD facilities where pediatric ESRD dialysis is performed. As a result, this population may be underserved and disadvantaged with respect to access to ESRD care. Additional payment to those ESRD facilities treating Pediatric ESRD Patients would thereby benefit this potentially underserved and

disadvantaged population of Pediatric ESRD patients. Additionally, this would have a beneficial financial impact on the ESRD facilities, both pediatric and non-pediatric, that serve this pediatric population.

We are proposing that this payment adjustment be budget neutral, which would lead to an estimated decrease of \$0.12 to the ESRD PPS base rate, corresponding to a budget neutrality factor of 0.99954. This relatively small adjustment would represent less than a twentieth of a percent of the total ESRD PPS base rate. However, we recognize that any decrease in the base rate would represent a monetary loss to ESRD facilities. As stated above, our analysis indicates that this proposed transfer would be reasonable given the likelihood that the methodology used in the case-mix adjusters attributed some pediatric costs to the general population. However, should future analysis of the stratified pediatric cost data indicate that pediatric ESRD renal dialysis services costs are less than 40 percent higher than adult costs, this proposed budget neutral decrease (if finalized as proposed) would mean that the treatments for adult patients with ESRD were slightly underpaid during this proposed 3-year period. In either case there would be a risk of underpayment for one group of patients. We believe that using the mean estimate of the analysis would provide us with the best approach for achieving payment accuracy while we collect additional data. Additionally, the health equity implications of potentially underpaying for Pediatric ESRD Patients receiving dialysis by 20 percent would be significantly higher than the implications of potentially underpaying for adult patients by a less than 0.1 percent. In CY 2021 there were 116 ESRD facilities that furnished more than 2 percent of their dialysis treatments to Pediatric ESRD Patients, out of 7882 total ESRD facilities. These ESRD facilities are a relatively small group, but they are critical for the care of Pediatric ESRD Patients. For these reasons, we believe that the expected benefits for the proposed TPEAPA would outweigh the costs.

(6) Request for Comments on This Proposal

We believe that providing this proposed 30 percent TPEAPA for calendar years 2024, 2025, and 2026 would be the best approach for improving payment accuracy until more precise data is available. However, we acknowledge that in any case there is a risk of making payments which are higher or lower than appropriate. We

are seeking comment on this proposal for an additional 30 percent payment adjustment for renal dialysis services furnished to Pediatric ESRD Patients for 3 calendar years, effective January 1, 2024, and on any alternative add-on payment adjustment amounts, including the 10 percent payment adjustment discussed earlier in this section of the proposed rule.

h. Proposed Reporting Policy for Unused and Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS (1) Background

As discussed in the CY 2023 PFS final rule (87 FR 69710), many drugs and biological products that are payable under Medicare Part B are dosed in a variable manner such that the entire amount identified on the vial or package is not administered to the patient. For example, many drugs are dosed based on the patient's body weight or body surface area (BSA). Often, these drugs are available only in single-dose containers. As stated in U.S. Food and Drug Administration (FDA) guidance for industry,²² a single-dose container is designed for use with a single patient as a single injection or infusion. The labeling for a drug packaged in a single-dose container typically includes statements instructing users to discard unused portions. When the labeling instructs a health care provider to discard the amount of drug that was unused (that is, the discarded amount) from a single-dose container or other single-use package of a drug after administering a dose to a Medicare beneficiary, the program provides payment for the unused and discarded amount, as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier (drug amount discarded/not administered to any patient) is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used to report the amount of a drug that is discarded and eligible for payment.

Beginning on January 1, 2017, CMS revised the Medicare Part B JW modifier policy to require the uniform use of the modifier for all claims for separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, in order to more effectively identify and monitor billing and payment for

²² <https://www.fda.gov/media/117883/download>.

discarded amounts of drugs.^{23 24} The policy does not apply to drugs that are not separately payable, such as packaged hospital outpatient prospective payment system (OPPS) drugs or those administered in federally qualified health centers (FQHCs) or rural health clinics (RHCs).

In the CY 2023 PFS final rule (87 FR 69718 through 69719), we codified our existing policy as discussed in the prior paragraph in Chapter 17 of the Medicare Claims Processing Manual, and required that billing providers report the JW modifier for all separately payable drugs with discarded drug amounts from single-dose containers or single-use packages payable under Part B, beginning January 1, 2023. These changes were promulgated in connection with the implementation of

the discarded drug refund program under section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021). In that same CY 2023 PFS final rule (87 FR 69722), we responded to commenters who requested we exempt drugs paid for under the ESRD PPS bundled payment from the discarded drug refund policy. One commenter expressed concern regarding how implementation of the discarded drug refund might inadvertently impact ESRD products, including those used by home dialysis patients (for example, Extraneal, a peritoneal dialysis solution). In response to those comments, we clarified that units for drugs that are packaged under the Medicare ESRD PPS were not subject to the JW modifier policy or the discarded drug refund.

In the same CY 2023 PFS final rule, CMS also finalized a proposal to require billing providers to report the JZ modifier for all such drugs with no discarded drug amounts, beginning no later than July 1, 2023. Specifically, as discussed in the CY 2023 PFS proposed rule (87 FR 46058), we proposed to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. We stated that to align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single-dose containers or single-use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. Table 9 below provides additional information about these modifiers.

TABLE 9 – JW and JZ Short and Long Descriptors

MODIFIER	SHORT DESCRIPTOR (28-character limit)	LONG DESCRIPTOR
JW	Discarded drug not administered	Drug amount discarded/not administered to any patient
JZ	Zero drug wasted	Zero drug amount discarded/not administered to any patient

We explained that on all claims for single-dose containers or single-use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We noted that we believed the JZ modifier requirement would not increase burden on the provider, because under the current JW modifier policy, the provider already needs to determine whether or not there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. We finalized the JZ modifier requirement in the CY 2023 PFS final rule. Lastly, we noted in the CY 2023 PFS final rule that we would begin claims edits for both the JW and JZ modifier beginning October 1, 2023 (87 FR 69179). Additional details can be found in Chapter 17 of the Medicare Claims Processing Manual and the JW/

JZ modifier frequently asked questions (FAQ) document.²⁵

(2) Current Reporting of the JW Modifier Under the ESRD PPS

As discussed in the previous section, the Medicare Part B JW modifier policy generally does not apply to drugs that are not separately payable. The ESRD PPS statute generally requires a single bundled payment for renal dialysis services. Specifically, section 1881(b)(14)(A)(i) requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The only exception is for oral-only drugs, as defined at § 413.234(a), which are currently paid separately under Medicare Part D. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. We note that although

the ESRD PPS includes certain add-on payment adjustments such as the TDAPA and TPNIES, these are adjustments to the ESRD PPS base rate and therefore part of the single payment made under the ESRD PPS; these payment adjustments are not separate payments. For example, as described in our TDAPA implementation guidance issued August 4, 2017, and updated January 10, 2018, available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf>, the methodology used to calculate the per treatment payment amount incorporates the cost of the drugs that are paid for using the TDAPA.

Although renal dialysis drugs and biological products paid for under the ESRD PPS are not considered “separately billable” and are not subject to the general Part B JW modifier policy discussed in the prior paragraph, CMS has previously issued guidance on the use of the JW modifier on ESRD PPS claims for certain circumstances. Chapter 8, section 60.4.5.1 of the

²³ CR6603: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf>.

²⁴ MLN Matters® Number MM9603: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf>.

²⁵ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>.

Medicare Claims Processing Manual pertains to self-administered supplies of ESAs.²⁶ Under current guidance, when billing for discarded amounts of drugs in accordance with the policy in chapter 17 of this manual, section 40.1, the provider must bill for discarded amounts on a separate line item with the modifier JW. The line item date of service should be the date of the last covered administration according to the plan of care or, if the patient dies, use the date of death. More specifically, in Chapter 17, section 40.1 of the Medicare Claims Processing Manual,²⁷ we state that multi-use vials are not subject to payment for discarded amounts of drug or biological products, with the exception of self-administered ESAs by Method I home dialysis patients, for whom an ESRD facility furnishes and bills for renal dialysis services.²⁸ Current guidance in Chapter 17, section 40.1 of the Medicare Claims Processing Manual states that the ESRD facility must bill the program using the JW modifier for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. We note that separate payment is not made for ESAs under the ESRD PPS; however, ESAs are eligible for outlier payments when the criteria in § 413.237 are met.

Most recently, the March 15, 2022 Change Request²⁹ that established the TDAPA for KorsuvaTM (difelikefalin), instructs facilities to use the JW modifier to report the amount of difelikefalin that is discarded and eligible for payment under the ESRD PPS. We note that based on the latest available data, nearly 40 percent of the TDAPA expenditures for those drugs that were reported in 2022 represented discarded amounts reported using the JW modifier. This represents

approximately \$1.3 million in TDAPA expenditures for discarded amounts of difelikefalin. Overall, our analysis of Medicare claims data from 2017 to 2021 finds that approximately 2 percent of ESRD PPS claims indicate discarded or unused portions of drugs or biological products through use of the JW modifier. From 2017 to 2021, we estimate that the total amount of unused product billed from 2017 to 2021 and paid for under the ESRD PPS is approximately \$22 million.

Under our current policy, we do not reduce the single payment under the ESRD PPS for any discarded amounts of renal dialysis drugs or biological products that are reported with the JW modifier. Furthermore, when calculating any adjustments to the ESRD PPS base rate for the TDAPA or outlier payments, we include all units of renal dialysis drugs and biological products billed on the claim for which an adjustment is made, including any discarded amounts of such drugs and biological products. Additionally, we have previously established in the CY 2012 ESRD PPS final rule (76 FR 70243 through 70244) that ESRD facilities may only report units and charges for drugs and biological products actually purchased and may not bill for overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling. Additionally, we explained that consistent with prior rulemaking, under our authority in section 1881(b)(14)(D)(ii) of the Act, we were adopting the average sales price (ASP) policy on overfill for purposes of calculating the outlier payment. That is, we adopted a policy to exclude overfill units of drugs and biological products which exceed the amount indicated on the vial or package labeling from consideration for the purposes of calculating outlier payments. We stated we believe the use of the ASP policy for purposes of calculating the outlier payment is appropriate because we believe overfill does not represent a cost to the ESRD facility; thus, overfill should not factor into our determination of outlier payments.

In summary, our longstanding policy for payment under the ESRD PPS, including the calculation of the TDAPA and outlier payment adjustments, includes payment for units of renal dialysis drugs and biological products billed with the JW modifier, but does not allow payment for overfill units. That is, the current ESRD PPS payment policy is consistent with the broader Medicare Part B policy to pay for the unused and discarded amount, as well as the dose administered, up to the

amount of the drug indicated on the vial or package labeling.

(3) Proposed ESRD PPS Policy for Reporting of Discarded Amounts of Renal Dialysis Drugs and Biological Products

As discussed in section II.B.1.j of this proposed rule, we are undertaking analysis of ESRD PPS claims and cost report data in order to better understand the patient-specific costs associated with furnishing renal dialysis services to Medicare beneficiaries. We believe that in order to most appropriately consider potential refinements to the ESRD PPS case-mix adjustments in the future, it is important to understand and have consistent data about the costs associated with the quantities of the renal dialysis drugs and biological products that are actually used by ESRD beneficiaries. This is consistent with our longstanding policy principles, which are reflected by our policy for billing for unused amounts of renal dialysis drugs and biological products under the ESRD PPS. In the CY 2016 ESRD PPS final rule (80 FR 69033), we discussed our existing policy since the inception of the ESRD PPS that all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. We stated that ESRD facilities should use the best information they have in determining the amount expected to be taken in a given month, including fill information from the pharmacy and the patient's plan of care. We noted that any billing system changes to effectuate this change needed to be made as soon as possible, as this requirement had been in effect since the ESRD PPS began in 2011. This policy is also discussed in the Medicare Benefits Policy Manual, Pub. 100–02, Chapter 11, section 20.3.C.

Consistent with our longstanding billing policies for unused amounts of drugs and biological products and consistent with the requirements for the uniform use of the JW modifier for all claims for separately payable drugs under Part B since 2017, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs, we are proposing to require ESRD facilities to report accurate and consistent data about discarded amounts of single-dose renal dialysis drugs and biological products paid under the ESRD PPS. Further, section 1881(b)(2)(B) of the Act requires the Secretary to prescribe in regulations

²⁶ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf>.

²⁷ <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>.

²⁸ Prior to the ESRD PPS, a Medicare ESRD beneficiary could elect to obtain home dialysis equipment and supplies from a supplier that was not a Medicare approved dialysis facility. This was referred to as Method II home dialysis. In the CY 2011 ESRD PPS final rule (75 FR 49061), we stated that all costs associated with home dialysis services (both Method I and Method II) are included in the composite portion of the two equation model, and we stated that effective January 1, 2011, all home ESRD patients would be considered Method I home patients and all Medicare payments for home dialysis services would be made to the ESRD facility.

²⁹ <https://www.cms.gov/files/document/r11295CP.pdf>.

any methods and procedures to determine the costs incurred by ESRD facilities in furnishing renal dialysis services to beneficiaries with ESRD, and to determine payment amounts for part B services furnished by such ESRD facilities.

Under our longstanding policy, payment is made under the ESRD PPS bundled payment for discarded amounts of renal dialysis drugs and biological products, and such discarded amounts are included in the calculation of the ESRD PPS base rate and any applicable adjustments, such as the TDAPA and the outlier adjustment. Therefore, consistent with the current JW and JZ reporting requirements that were finalized in the CY 2023 PFS final rule for separately payable Part B drugs, we are proposing to require that beginning no later than January 1, 2024, ESRD facilities must report information on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). We are also proposing that ESRD facilities must document any discarded amounts in the beneficiary's medical record. Additionally, we are proposing to require ESRD facilities to report the JZ modifier for all such renal dialysis drugs and biological products with no discarded amounts, beginning no later than January 1, 2024. We are proposing to codify these reporting requirements in regulation at § 413.198(b)(5) and (6).

Under this proposal, the amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is administered would be billed on one line (reflected as billing units in the unit field) and any discarded amounts would be billed on a separate line with the JW modifier (reflected as billing units in the unit field). If a renal dialysis drug or biological product from a single-dose container or single-use package is administered and there are no discarded amounts, then we are proposing that a single line would be billed on the claim form with the JZ modifier and the billing units in the unit field. Therefore, on all claims for renal dialysis drugs and biological products from single-dose containers or single-use packages payable under the ESRD PPS, we are proposing that either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded

amounts. We are proposing that claims for renal dialysis drugs and biological products from single-dose containers or single-use packages that do not report either the JW or JZ modifier may be returned as un-processable until claims are properly resubmitted.³⁰ If this proposal is finalized, CMS would publish information about which HCPCS codes would be identified as single-dose containers or single-use package renal dialysis drugs and biological products subject to required reporting of the JW or JZ modifier. We also would plan to issue guidance regarding additional operational considerations and billing instructions specific to the proposed reporting requirements for these products, if finalized.

We are clarifying that, under our proposal, ESRD facilities would not be required to document in the beneficiary's medical record when there are no discarded amounts. Lastly, we are reiterating that, as discussed in the CY 2023 PFS final rule (87 FR 69722), units for renal dialysis drugs and biological products that are bundled under the Medicare ESRD PPS are not subject to the Medicare Part B discarded drug refund program and would continue to be exempted from the Medicare Part B discarded drug refund. We are also clarifying that for any oral-only drugs, as defined in § 413.234(a), to the extent that any such drugs are produced in single-dose containers or single-use packaging, this proposed reporting requirement would not apply until such drugs are paid for under the ESRD PPS.

We believe that this proposed reporting requirement would enable CMS to obtain more reliable information about the extent to which the costs of providing renal dialysis drugs and biological products represent amounts that beneficiaries use as well as amounts that are discarded. We believe this is particularly important because under Medicare Part B, beneficiaries are responsible for paying a 20 percent coinsurance. As noted above, nearly 40 percent of TDAPA expenditures in CY 2022 represented discarded amounts of renal dialysis drugs and biological products. Medicare beneficiaries, therefore, paid approximately \$260,000 in copayments for these discarded amounts. While this currently

represents a small amount of payments overall, the cost for discarded renal dialysis drugs and biological products is borne by a very small population of beneficiaries. It is important for CMS to understand the full scope of expenditures, including expenditures that may be incurred by beneficiaries, for discarded amounts of renal dialysis drugs and biological products in the future, which may be more expensive or more widely used than the current drug that is being paid for using the TDAPA under the ESRD PPS. Thus, we are not proposing in this rule to alter payments to ESRD facilities based on the amounts of discarded renal dialysis drugs and biological products reported, but data collected through adoption of the JW and JZ modifier reporting requirements discussed in this section may inform future payment policies, which would be proposed through future notice and comment rulemaking if appropriate.

Based on our analysis of ESRD PPS claims, as well as the billing guidance in sections 8 and 17 of the Medicare Claims Processing Manual, we believe the proposed JW modifier requirement reflects current practices for ESRD facilities, and would not significantly increase burden for ESRD facilities. Additionally, we believe the proposed JZ modifier requirement would not increase burden on ESRD facilities, because under the current guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place in order to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single-dose container or single-use package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form.

Furthermore, we note that while renal dialysis drugs and biological products that are paid under the ESRD PPS are not considered separately payable, ESRD facilities are permitted to bill and receive separate payment using the AY modifier for drugs and biological products that are not related to the treatment of ESRD. Although we have noted that renal dialysis drugs and biological products paid under the ESRD PPS are not subject to the Medicare Part B drug refund program or the current JW or JZ reporting requirements, any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would be subject to such policies under Medicare Part B. Therefore, we believe that most ESRD facilities should already be reporting the JW and JZ modifiers in

³⁰ Under the basic requirements for all claims at § 424.32(a)(1), a claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions. Chapter 1 of the Medicare Claims Processing Manual, section 70.2.3.1 states that submissions that are found to be incomplete or invalid are returned to the provider (RTP).

such circumstances, and would reasonably be able to report these modifiers for renal dialysis drugs and biological products as well. We welcome comments on this assumption and on these proposed JW and JZ reporting requirements for the ESRD PPS.

i. Proposed New Add-On Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

(1) Background on the TDAPA

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at 42 CFR 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed since the implementation of the ESRD PPS in 2011. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69014), when we implemented the ESRD PPS, drugs and biological products were grouped into functional categories based on their action. This was done to add new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs are commercially available so beneficiaries have access to them. As we stated in the CY 2011 ESRD PPS final rule, we did not specify all the drugs and biological products within these categories, because we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified, and we wanted the ability to reflect new drugs and biological products developed or changes in standards of practice (75 FR 49052).

In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077). We finalized a policy in the CY 2016 ESRD PPS final rule that if a new renal dialysis injectable or IV product

falls within an existing functional category, the new injectable drug or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. We noted in that rule that the ESRD bundled market basket update is used to increase the ESRD PPS base rate annually and accounts for price changes of the drugs and biological products. We also finalized in the CY 2016 ESRD PPS final rule that, if the new renal dialysis injectable or IV product does not fall within an existing functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA codified in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. The new injectable or IV product is not eligible as an outlier service during the TDAPA period. We established that following the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

In the CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, we revised the regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by FDA as Type

3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the “parent NDA” is a Type 3, 5, 7, or 8, effective January 1, 2020.

Under our current TDAPA policy at § 413.234(c), a new renal dialysis drug or biological product that falls within an existing ESRD PPS functional category is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the ESRD PPS base rate will not be modified. If the new renal dialysis drug or biological product does not fall within an existing ESRD PPS functional category, it is not considered included in the ESRD PPS base rate, and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not for less than 2 years. After the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological product in the ESRD PPS bundled payment.

As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a potential pathway toward a potential ESRD PPS base rate modification (83 FR 56935). For the complete history of the TDAPA policy, including the pricing methodology, please see the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CY 2019 ESRD PPS final rule (83 FR 56932 through 56948), and CY 2020 ESRD PPS final rule (84 FR 60653 through 60681).

(2) Request for Information in the CY 2023 ESRD PPS Proposed Rule

In the CY 2023 ESRD PPS proposed rule (87 FR 38522 through 38523), we summarized the concerns of interested parties and issued a request for information about methods that could be used to develop an add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA. We explained that since 2019, dialysis associations and pharmaceutical

representatives have expressed concerns to CMS about payment following the TDAPA period for new renal dialysis drugs and biological products that are paid for using the TDAPA. We noted that these interested parties have asserted that unless money is added to the ESRD PPS base rate for these drugs and biological products, similar to what occurred with calcimimetics (85 FR 71406 through 71410), then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when the TDAPA period ends. Further, these interested parties cautioned that uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA period. We noted that to date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. We stated that there have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result, CMS does not yet have data on other drugs or biological products in order to evaluate the specific risks and access challenges that interested parties have raised.

We also discussed that, as mentioned in the CY 2019 (83 FR 56941) and CY 2020 (84 FR 60672 and 60693) ESRD PPS final rules, many commenters have suggested a rate-setting exercise at the end of the TDAPA period for all new renal dialysis drugs and biological products. We responded to those comments by noting that we do not believe adding dollars to the ESRD PPS base rate would be appropriate for new drugs that fall into the ESRD PPS functional categories, given that the purpose of the TDAPA for these drugs is to help ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provide additional payments for such associated costs, and promote competition among the products within the ESRD PPS functional categories. In addition, we explained that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. We stated that under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and that there would be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. We noted

that a central objective of the ESRD PPS and of prospective payment systems in general is for ESRD facilities to be efficient in their resource use.

We also noted that price changes to the ESRD PPS bundled payment are updated annually by the ESRDB market basket update, which includes a pharmaceutical cost category weight. In addition, we explained that our analysis of renal dialysis drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time for some high volume formerly separately billable renal dialysis drugs, relative to overall market basket growth. Therefore, we stated that we believe that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

We noted that section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(I) for pediatric providers of services and renal dialysis facilities; (II) by a geographic index, such as the index referred to in section 1881(b)(12)(D), as the Secretary determines to be appropriate; and (III) for providers of services or renal dialysis facilities located in rural areas. Regarding the patient access concerns that we discussed in the CY 2023 ESRD PPS proposed rule, we stated that we were considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends. We noted that any add-on payment adjustment would be subject to the Medicare Part B beneficiary co-insurance payment under ESRD PPS.

In the CY 2023 ESRD PPS proposed rule, we presented four potential methods that we were considering, which we noted could be used to develop an add-on payment adjustment for these drugs and biological products. We noted that the methods presented differed in terms of which formerly separately billable renal dialysis drugs and biological products would be considered for a potential add-on payment adjustment. We further noted that under these potential options, we would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category. The four options are summarized as follows:

- Reconcile the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products. For example, if the reduction in the cost of all formerly separately billable renal dialysis drugs and biological products per treatment excluding the renal dialysis drug or biological product that was paid for using the TDAPA is \$5 and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10, the add-on payment adjustment per treatment would be \$10 minus \$5, which is \$5. The reductions in formerly separately billable renal dialysis drug and biological products expenditures per treatment would be calculated by using the difference between these expenditures in the most recent year with claims data available and these expenditures in the current base year for the ESRDB market basket, which is CY 2020. We provided the following example: If the rule year for which we are calculating the add-on payment adjustment is CY 2023 and the base year for the ESRDB market basket is CY 2020, the reduction in formerly separately billable renal dialysis drugs and biological products expenditures would be the difference between these expenditures in CY 2021 (the year with the most recent claims data) and those in CY 2020.

- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products, where such reduction can be empirically attributed to the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the utilization of the renal dialysis drug or biological product that was paid for using the TDAPA was found to be statistically associated with reduction in expenditure of one drug in an ESRD PPS functional category amounting to \$1 per treatment, and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10, the add-on payment adjustment per treatment would be \$10 minus \$1, which is \$9.

- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs that fall into one or more ESRD PPS

functional categories, where such expenditure reduction is data-driven, based on end action effect, to be attributable to the renal dialysis drug or biological product that was paid for using the TDAPA. Such a data-driven determination would be made by CMS. For example, if the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10 and the reduction in the expenditure for other clinically related formerly separately billable renal dialysis drugs is \$0.50 per treatment, the add-on payment adjustment would be \$10 minus \$0.50, which is \$9.50.

- Only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the per treatment cost of the renal dialysis drug or biological product that was paid for using the TDAPA is \$10, this would be the amount of the add-on payment adjustment.

Following the discussion in the CY 2023 ESRD PPS proposed rule about these potential methodologies, we issued a request for information within that proposed rule (87 FR 38523) to seek feedback from the public on the following questions.

- Is an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed? If so, why? What criteria should CMS establish to determine which renal dialysis drugs or biological products would be included in the calculation for an add-on payment adjustment after the TDAPA period ends?

- If an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period is needed, are the methods discussed in section II.D.4 of the CY 2023 ESRD PPS proposed rule sufficient to address the add-on payment adjustment?

++ Which method would be most appropriate?

++ Are there changes to the methodologies that CMS should consider to improve our ability to align payment for renal dialysis services with resource utilization? Please provide as much detail as possible.

++ Are there other methodologies that CMS should consider? Please provide as much detail as possible.

We noted that while we would not be responding to specific comments submitted in response to this RFI, we intended to use this input to inform future policy development. We stated that any potential payment policies

related to this RFI would be proposed through a separate notice and comment rulemaking.

We provided a high-level summary of responses to this RFI in the CY 2023 ESRD PPS final rule (87 FR 67219 through 67220) and noted that we would publish more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/EducationalResources>. We noted that we received 27 public comments regarding our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large, non-profit health system; and MedPAC.

In the CY 2023 ESRD PPS final rule, we stated that most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the adoption of new renal dialysis drugs and biological products, and that most commenters stated that they supported CMS allowing all new renal dialysis drugs and biological products to be eligible to receive an add-on payment adjustment after the TDAPA period ends. However, we noted that MedPAC opposed this type of add-on payment adjustment by stating that it would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices. We also noted that MedPAC recommended that CMS limit the add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment.

We further noted in the CY 2023 ESRD PPS final rule that several commenters stated they supported reconciling the expenditure of the new renal dialysis drug or biological product with any reduction in expenditures for other formerly separately billable renal dialysis drugs that are clinically or statistically related to the introduction of the new renal dialysis drug in the bundle. Several commenters expressed their belief that the FDA-approved label should be used to determine the primary indication and clinical association, rather than end-action effect. MedPAC expressed opposition to calculating any add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends, but noted that if an add-on payment adjustment were

applied, it would be appropriate to use an offset, similar to the approach used with the TPNIES, to avoid duplicative payment for renal dialysis services already included in the ESRD PPS base rate.

(3) Proposed Add-On Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

As discussed previously, section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Based on the public comments received regarding the RFI in the CY 2023 ESRD PPS proposed rule,³¹ we believe it is appropriate to propose, beginning January 1, 2024, an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We note that this proposed post-TDAPA payment adjustment would not apply to new renal dialysis drug or biological products used to treat or manage a condition for which there is not an ESRD PPS functional category, because we have already established a policy to modify the ESRD PPS base rate for such products, if appropriate, after the TDAPA period ends, to account for the products in the ESRD PPS bundled payment (§ 413.234(c)(2)(i)).

We agree with commenters who expressed concerns that the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs. Several commenters asserted that the outlier adjustment and the market basket updates cannot adequately account for these costs, and several organizations noted that if renal dialysis drugs and biological products with significant costs were adopted under the outlier policy, the threshold to qualify for outlier payments would increase dramatically, thus adversely affecting access to products traditionally eligible for the outlier payment adjustment. Commenters expressed that this increase in the outlier threshold may also raise health equity concerns because, as we noted in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67171), the outlier adjustment protects access for beneficiaries whose care is unusually costly. We recognize that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the

³¹ <https://www.cms.gov/files/document/cy-2023-esrd-pps-payment-after-tdapa-rfi-summary-comments.pdf>.

TDAPA, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries. Additionally, several commenters raised concerns about the ability of the market basket to account for the cost of new renal dialysis drugs and biological products. These commenters referred to a Moran study³² suggesting that the drug proxies historically used in updating the ESRD PPS base rate have not adequately accounted for the costs of non-ESA drugs under existing functional categories. While we continue to believe that the market basket price proxies are the best available information for projecting the future costs of renal dialysis drugs and biological products, and that they provide an adequate mechanism for projecting future ESRD PPS cost growth, we recognize that there is additional uncertainty about future trends in the expenditures for new renal dialysis drugs and biological products, including trends in pricing and utilization of such drugs and any equal substitutes such as generic drugs.³³ We believe these trends could be more effectively analyzed by collecting additional ESRD facility cost data following the 2-year TDAPA period. We recognize that although the TDAPA for drugs and biological products in existing ESRD PPS functional categories enables ESRD facilities to incorporate new renal dialysis drugs and biological products into their businesses, additional support may be needed to assure continued access to such drugs and biological products for Medicare beneficiaries and to support ESRD facilities' long-term planning and budgeting. We also recognize the importance of providing an appropriate pathway for ESRD facilities to incorporate new renal dialysis drugs and biological products into their business operations. In the CY 2019 ESRD PPS final rule in which we first established the 2-year TDAPA period for new renal dialysis drugs and biological products in an existing ESRD PPS functional category (83 FR 56934), we acknowledged that ESRD facilities have unique circumstances with regard to implementing new drugs and biological products into their standards of care. For example, we stated that when new drugs are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new

therapies in their care plans. We noted that newly launched drugs and biological products can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, we stated that practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. We noted that we agreed this uptake period would be best supported by the TDAPA pathway because it would help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. We continue to believe that the 2-year TDAPA period is appropriate and achieves its stated goals. However, we also recognize that continuity and predictability is an integral part of ESRD facilities' ongoing business operations. We agree with commenters' concerns that a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products. We are therefore proposing to establish a new transitional add-on payment adjustment that would provide an appropriate transition of the level of payment following the TDAPA period for these drugs. For ease of reference, we are proposing to refer to this proposed add-on payment adjustment as the post-TDAPA add-on payment adjustment. Our goals for the post-TDAPA add-on payment adjustment are to ensure that in circumstances when the ESRD PPS base rate is not modified because a new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category and is therefore considered included in the ESRD PPS bundled payment, payment after the TDAPA is not a barrier to Medicare beneficiaries' access to such new products. We also want to support ESRD facilities' long-term planning with respect to continuing to budget and plan for new renal dialysis drugs and biological products that ESRD facilities have incorporated into their businesses during the TDAPA period. In addition, in accordance with the goals of prospective payment under the ESRD PPS, our goal for the post-TDAPA add-on payment adjustment is to incentivize ESRD facilities to be efficient in the use of resources.

We do not agree with MedPAC's statement that a post-TDAPA add-on payment adjustment would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices. As

discussed in the following section, we are proposing to apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments following the end of the TDAPA period and would not limit the adjustment to claims that include the new renal dialysis drug or biological product. We believe that this proposed methodology would appropriately align incentives for ESRD facilities and would support competition with existing drugs, because payment for an individual claim would not be dependent on individual utilization of the new renal dialysis drug or biological product. Thus, we anticipate that the proposed methodology would create incentives for ESRD facilities to efficiently allocate resources in a way that would be consistent with the principles of prospective payment. We note that when Erythropoietin (EPO) switched from being separately payable to being paid for under the ESRD PPS beginning in CY 2011, these incentives to efficiently allocate resources resulted in decreases in expenditures for these drugs while also providing increased payment to ESRD facilities that supported beneficiaries' access to the new renal dialysis drugs and biological products. Because of these incentives, which would encourage ESRD facilities to efficiently allocate resources, we anticipate that the proposed methodology would not encourage higher launch prices for new renal dialysis drugs and biological products, as manufacturers would need to price such drugs and biological products appropriately to compete with existing drugs and biological products included in the ESRD PPS bundled payment.

We also do not agree with MedPAC's recommendation that CMS limit the post-TDAPA add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment. As stated previously, we recognize that continuity and predictability is integral to ESRD facilities' operations, and we do not believe that this principle applies only to drugs and biological products that show a substantial clinical improvement. As we explained in the CY 2023 ESRD PPS final rule (87 FR 67189), the intent of the ESRD PPS functional category framework is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician. As we further explained in the CY 2023 ESRD PPS final rule, the functional category structure helps to ensure the ESRD

³² Kidney Care Partners. August 4, 2022. Comment Letter. <https://kidneycarepartners.org/wp-content/uploads/2022/08/KCP-PPS-Comment-Letter-Part-1-Final.pdf>. Accessed May 16, 2023.

³³ <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers>.

patient has broad access to all renal dialysis service drugs, which is a distinct benefit to the patient. In addition, the structure of the functional categories helps to ensure the treating physician has a broad array of drugs to meet the specific, individual needs of each ESRD patient, including differing pharmaceutical profiles, comorbidities, contra-indications with other drugs the patient may be taking, and personal patient preference (87 FR 67189). We do not believe that limiting the post-TDAPA add-on payment adjustment based on CMS's determination of substantial clinical improvement would align with this stated intent of the ESRD PPS functional category framework to support broad access to all renal dialysis service drugs. We further note that the current TDAPA exclusion criteria under § 413.234(e) consider FDA's determination of the drug's new drug application (NDA) type or approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which is less subjective than a determination of substantial clinical improvement. Furthermore, we believe that our proposed methodology for the post-TDAPA add-on payment adjustment would incentivize ESRD facilities' efficient use of resources, because as previously stated, payment for an individual claim would not be dependent on individual utilization of the new renal dialysis drug or biological product. Accordingly, we believe that under our proposed methodology, for new renal dialysis drugs and biological products that are not a substantial clinical improvement over existing renal dialysis drugs and biological products, utilization would diminish over time and the amount of the post-TDAPA add-on payment adjustment would decline accordingly. As discussed earlier in this proposed rule, we anticipate that the incentives for ESRD facilities under the proposed methodology for the post-TDAPA add-on payment adjustment would result in competition between new and existing renal dialysis drugs and biological products, and that this competition would serve to drive down prices of such new renal dialysis drugs and biological products over time.

We are proposing to calculate the post-TDAPA add-on payment adjustment following the methodology described in the following subsections for any new renal dialysis drug or biological product that is paid for using the TDAPA under § 413.234(c)(1). We are proposing that the post-TDAPA add-on payment adjustment would be applied for a period of 3 years following the end of the TDAPA period for those

products. We believe that a 3-year payment period would provide sufficient time for CMS to analyze cost reports that include costs for the new renal dialysis drug or biological product paid for using the TDAPA under the ESRD PPS, in order to incorporate changes as appropriate to the ESRD PPS market basket price proxies. The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. The proposed 3-year payment period for the post-TDAPA add-on payment adjustment would allow CMS to evaluate how the new drug or biological product affects the overall mix of renal dialysis drugs and biological products in the ESRDB market basket and to determine the appropriate price proxies for such new drug or biological product. We note that for new renal dialysis drugs and biological products that are not considered included in the ESRD PPS base rate, the TDAPA is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years. Similarly, as described earlier in this paragraph, we are proposing a 3-year payment period for the post-TDAPA add-on payment adjustment, which would enable the collection and analysis of sufficient cost report information and would address the concerns that commenters raised about the effectiveness of the ESRD PPS market basket price proxies to account for the costs of new renal dialysis drugs and biological products going forward by allowing CMS to incorporate data showing trends in use over an adequate period of time. Additionally, we believe that a 3-year period for the post-TDAPA add-on payment adjustment would be appropriate and consistent with the transition period that we finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (79 FR 49162). We finalized the transition period for CY 2011 through CY 2013 in order to comply with the requirement of section 1881(b)(14)(E)(i) of the Act to provide a 4-year phase-in of the payment amount under the ESRD PPS, where full implementation of the ESRD PPS payment would occur beginning in the fourth year, CY 2014. We are proposing a similar timeline to provide an appropriate transition for new renal dialysis drugs and biological products in existing ESRD PPS functional

categories, which are not eligible for a modification to the ESRD PPS base rate. Based on the experience of ESRD facilities during the 4-year phase-in from CY 2011 to CY 2014, ESRD facilities would be familiar with this timeline for phasing in major changes that impact their long-term planning and budgeting. Lastly, in the interest of transparency, we note that this 3-year period would provide time for analysis of utilization data for public awareness about the potential need for refinements to the ESRD PPS. Therefore, we are proposing to calculate and apply the post-TDAPA add-on payment adjustment for a period of 3 years following the end of the TDAPA period, with no post-TDAPA add-on payment adjustment calculated beginning in the 4th year.

We are proposing that this post-TDAPA add-on payment adjustment would not be budget neutral, as discussed later in this proposed rule. We note that this proposed post-TDAPA add-on payment adjustment, if finalized, would be calculated for *Korsuva*TM, the only renal dialysis drug currently receiving the TDAPA, and that payment of this post-TDAPA add-on payment adjustment, if finalized, would begin April 1, 2024 at the end of the TDAPA period for *Korsuva*TM.

(a) Calculation of the Proposed Post-TDAPA Add-On Payment Adjustment

As discussed earlier in this section of the proposed rule, we are proposing to establish a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We are proposing to apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments beginning at the end of a new renal dialysis drug or biological product's TDAPA period. Specifically, we are proposing that the post-TDAPA add-on payment adjustment would begin 8 calendar quarters after the beginning of the first calendar quarter in which TDAPA payment is made for the new renal dialysis drug or biological product in an existing ESRD PPS functional category, and would end no later than the 12th calendar quarter after the last calendar quarter in which TDAPA payment is made. As discussed in the following paragraphs, we believe our proposed calculation of the post-TDAPA add-on payment adjustment would be the most appropriate to address the patient access concerns we discussed in the CY 2023 ESRD PPS proposed rule and in this section of the proposed rule, and the most consistent with the

principles of prospective payment. This proposal would apply the patient-level adjustment factors to the post-TDAPA add-on payment adjustment amount paid on each claim, which would ensure that ESRD PPS payment would support access to new renal dialysis drugs and biological products for beneficiaries with conditions that are costlier to treat, in alignment with our goals as stated earlier in this proposed rule. We are proposing to codify the payment of the post-TDAPA add-on payment adjustment as part of the per treatment payment amount at § 413.230(f). We are proposing to codify the methodology for calculating the post-TDAPA add-on payment adjustment at § 413.234(g). We are proposing to make additional changes under § 413.234(b) and (c) to address payment of the post-TDAPA payment adjustment.

In determining the proposed calculation of the proposed post-TDAPA add-on payment adjustment, we considered the comments that we received regarding the RFI in the CY 2023 ESRD PPS proposed rule. Some commenters expressed that new and innovative drugs may only be used by a small percentage of the dialysis population and suggested that an add-on payment adjustment should address patient-specific needs in order to support access.

First, we considered calculating the post-TDAPA add-on payment adjustment as the average cost for patients that used the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS, and applying the post-TDAPA add-on payment adjustment only to claims that include the new renal dialysis drug or biological product. However, we are concerned that such an approach would not align with the principles of prospective payment under the ESRD PPS. As we noted earlier in this proposed rule, a central objective of the ESRD PPS (and of prospective payment systems in general) is for ESRD facilities to be efficient in their resource use. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and CMS acknowledges there will be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. Additionally, we are concerned that such an approach would result in a substantial cost burden for beneficiaries who use the new renal dialysis drug or biological product, because they incur a 20 percent coinsurance under Part B for renal dialysis services. We do not

believe this approach would align with our priorities to reduce drug costs for Medicare beneficiaries. In contrast, our proposed methodology would apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments, which would result in a minimal increase in per-treatment coinsurance amounts for all beneficiaries. As discussed later in this section, we are proposing to apply the ESRD PPS patient-level adjustments to the post-TDAPA add-on payment adjustment for each treatment.

Next, we considered applying the post-TDAPA add-on payment adjustment based only on claims from ESRD facilities that used the new renal dialysis drug or biological product during the TDAPA period. However, like the previous option, we believe that limiting application of this add-on payment adjustment to claims from ESRD facilities that include the new renal dialysis drug or biological product would be inconsistent with the principles of prospective payment. As we discussed in the CY 2011 ESRD PPS final rule, there are patients whose medical treatment results in more costly care as well as those with less costly care, and the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient (75 FR 49045). Further, we are concerned that limiting the post-TDAPA add-on payment adjustment to claims from ESRD facilities that use the new renal dialysis drug or biological product could result in substantial overestimation of the post-TDAPA add-on payment adjustment, if more ESRD facilities begin using the new renal dialysis drug or biological product. As we discuss later in this proposed rule, we are proposing to apply this post-TDAPA add-on payment adjustment in a non-budget neutral manner. Therefore, we are concerned that an overestimation of the post-TDAPA add-on payment adjustment could result in an inappropriate increase in Medicare expenditures. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. We believe

that after the end of the TDAPA period, ESRD facilities will have made appropriate changes in their business models to adopt such products, and therefore any approach to a post-TDAPA add-on payment adjustment should apply equally to all ESRD PPS treatments, in order to apply the appropriate incentive structures for ESRD facilities' utilization of renal dialysis drugs and biological products and to continue to promote competition among the products within the ESRD PPS functional categories, including the new renal dialysis drug or biological product that was previously paid for using the TDAPA under the ESRD PPS. Furthermore, we believe that such an approach would help to support access to new renal dialysis drugs and biological products to the widest scope of beneficiaries. This is in line with CMS's commitment to advance health equity by supporting access to renal dialysis services.

Accordingly, we are proposing to apply the post-TDAPA add-on payment adjustment to each ESRD PPS treatment, and to adjust it for patient characteristics. In other words, the post-TDAPA add-on payment adjustment would be multiplied by the ESRD PPS patient-level adjustments under § 413.235. We believe this approach would appropriately adjust aggregate ESRD PPS payment to account for the new renal dialysis drugs and biological products in a way that is consistent with the principles of prospective payment, and would support beneficiary access to new renal dialysis drugs and biological products by recognizing the additional patient-specific needs associated with the existing ESRD PPS case-mix adjusters. We note that in order to calculate an appropriate post-TDAPA add-on payment adjustment, we would apply a case-mix standardization factor to the post-TDAPA add-on payment adjustment amount as discussed in the following paragraphs.

In addition, we considered the public comments regarding the need to reconcile estimated expenditures for a new renal dialysis drug or biological product with the declines in expenditures for related drugs. As we noted earlier in this proposed rule, commenters expressed support for establishing a methodology that would consider the decline in estimated expenditures for drugs that are clinically or empirically related to the new renal dialysis drug or biological product. Such a methodology would be highly complex and less transparent than other potential options that commenters suggested. Commenters noted various ideas that CMS would

need to consider when attempting to establish the offsetting financial effects of drugs and biological products that are either clinically or empirically-related to the new renal dialysis drug or biological product. For example, most commenters suggested that CMS use drugs with the same FDA clinical indication to offset the payment adjustment, in the interest of transparency and objectivity. However, some commenters, including MedPAC, noted that they do not believe that FDA determinations or ESRD PPS functional categories should be the basis of eligibility for the post-TDAPA payment adjustment, as CMS should make these determinations based on the specific needs of the Medicare population. We believe that such considerations based on specific population needs could be less transparent than alternative approaches, especially in situations when there could, in the future, be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments. We anticipate that it would be challenging for CMS to determine, within the annual rulemaking timeframes, the extent to which changes in the utilization of existing renal dialysis drugs and biological products are clinically or empirically related to utilization of a new renal dialysis drug or biological product paid for using the TDAPA. We note that the latest available data at the time of this proposed rulemaking includes less than a full year of TDAPA utilization. We anticipate that as additional data are collected, CMS would be able to analyze trends and may be able to retrospectively determine the extent of any substitution effects between new and existing renal dialysis drugs and biological products. Furthermore, the calculation of these offsets could involve multiple overlapping periods of time, which would further increase complexity and reduce transparency. As an alternative, we considered MedPAC's suggestion to align the methodology closer to that of the ESRD PPS TPNIES, wherein CMS pays a reduced percentage of the estimated incremental cost of a new product as a risk-sharing mechanism with ESRD facilities and to provide a disincentive for significant increases in drug prices. Under the TPNIES, CMS calculates the TPNIES amount as 65 percent of the MAC-determined price for certain new and innovative equipment and supplies (§ 413.236(f)). We believe this approach would have the same general effect of accounting for declines in other drug expenditures, while being significantly

less complex and more transparent. In the CY 2020 ESRD PPS final rule that established the 65 percent cost-sharing proportion for TPNIES, we stated that the goal of TPNIES was to support ESRD facility use of new and innovative renal dialysis equipment and supplies (84 FR 60692). In that same CY 2020 ESRD PPS final rule, we further stated in response to comments that we believe that we need to balance this goal with sharing risk for the new product (84 FR 60697). As noted earlier in this proposed rule, one goal of the proposed post-TDAPA add-on payment adjustment is to support continued access to new renal dialysis drugs and biological products and to support ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period. Additionally, as stated earlier in this section of this proposed rule, our goal is also to incentivize efficient use of resources, consistent with the principles of prospective payment under the ESRD PPS. We believe that applying a cost-sharing proportion of 65 percent to the proposed post-TDAPA add-on payment adjustment would effectively achieve these goals, because it would provide a significant level of payment that supports access for beneficiaries and long-term planning for ESRD facilities, while incentivizing ESRD facilities to efficiently allocate resources by sharing a significant portion of the cost with ESRD facilities. Furthermore, this proposed 65 percent cost-sharing factor would serve to further reduce the minimal cost-sharing burden of new renal dialysis drugs and biological products for beneficiaries, under the proposed post-TDAPA add-on payment methodology. Lastly, we note that for home dialysis machines that are capital-related assets that qualify for the TPNIES, our policy is to apply an offset to account for the amount of such capital-related assets in the ESRD PPS base rate. As we discussed previously, we considered applying an offset to the proposed post-TDAPA add-on payment adjustment; however, we believe that considerations based on specific population needs could be less transparent than applying a simple 65-percent risk-sharing percentage. Additionally, we noted that in the future, there could be multiple new renal dialysis drugs or biological products for which we would be calculating multiple offset adjustments, which would further increase complexity and reduce transparency. We are soliciting comments on whether there are other ways CMS could consider calculating an offset amount for the post-TDAPA payment

adjustment. Alternatively, we seek comment on if there are other ways CMS can ensure any growth in post-TDAPA add-on payment adjustment amounts is reasonable, such as not allowing increases to exceed inflation or other relevant metrics.

We are proposing to calculate the post-TDAPA add-on payment adjustment annually, based on the latest available full calendar quarter of average sales price (ASP) data, which would be consistent with the current policy for determining the basis of payment for the TDAPA. Under current policy, finalized in the CY 2020 ESRD PPS final rule (84 FR 60679), we pay the TDAPA based on 100 percent of ASP. If ASP is not available, we base the TDAPA payment adjustment on wholesale acquisition cost (WAC), and if WAC is not available, then we base payment on invoice pricing. As we stated in the CY 2020 ESRD PPS final rule, we continue to believe that after the TDAPA period, calculating the proposed post-TDAPA add-on payment adjustment for new renal dialysis drugs based on ASP, as compared to WAC or invoice pricing, would be the most appropriate choice for the ESRD PPS, and would strike the right balance in supporting ESRD facilities in their uptake of innovative, new renal dialysis drugs and biological products and limiting increases to Medicare expenditures. We propose to address the annual calculation of the post-TDAPA add-on payment adjustment in the annual proposed and final ESRD PPS rules for future years.

As discussed in section II.B.1.k, under current TDAPA policy, if CMS stops receiving ASP during the TDAPA period, then CMS will stop paying the TDAPA after 2 calendar quarters. Similarly, we believe that if drug manufacturers were to stop submitting ASP data for products that are included in the calculation of the proposed post-TDAPA add-on payment adjustment, and we had to revert to basing calculation of the post-TDAPA add-on payment adjustment on WAC or invoice pricing, we would be overpaying for the proposed add-on payment adjustment. Therefore, we are proposing to make payment of the post-TDAPA add-on payment adjustment conditional on receiving ASP data. Because the post-TDAPA add-on payment adjustment would be calculated annually rather than quarterly, we are proposing that if CMS does not receive the latest full calendar quarter of ASP data for a drug that would be included in the calculation of the post-TDAPA add-on payment adjustment, then CMS would not include that drug in the calculation of the post-TDAPA add-on payment

adjustment for any future years. We are also proposing that if CMS stops paying the TDAPA for a drug or biological product because CMS stops receiving the latest full calendar quarter of ASP data, then we would not include that drug or biological product in the calculation of the post-TDAPA add-on payment adjustment for the next CY or any future CY. Consistent with our policy for calculating the TDAPA, as discussed in section II.B.1.k of this proposed rule, we are proposing that in situations when a manufacturer reports zero or negative sales, we would consider CMS to have received the latest full calendar quarter of ASP data, but we would calculate the post-TDAPA payment adjustment based on WAC, or if WAC is not available, on invoice pricing, in such circumstances.

Finally, we are proposing that for each of the 3 years for which this proposed post-TDAPA add-on payment adjustment would be paid, we would update the amount of the post-TDAPA add-on payment adjustment by the ESRD PPS market basket update to account for estimated future input price changes faced by ESRD facilities. We are soliciting comment on whether it would be more appropriate to consider using the growth in the market basket price proxy for the Pharmaceuticals cost category in the ESRDB market basket, rather than the market basket update.

Therefore, we are proposing to use the following calculation to determine the amount of the post-TDAPA add-on payment adjustment to be applied to each ESRD PPS treatment.

- Step 1, using the most recent available 12 months of claims data, calculate the total expenditure of the new renal dialysis drug or biological product being paid for using the TDAPA under the ESRD PPS. Total expenditure would be calculated by multiplying the latest available full calendar quarter of ASP data for the new renal dialysis drug or biological product by the quantity of units billed. If CMS does not receive the latest available calendar quarter of ASP data for a drug or biological product, then CMS would not apply the post-TDAPA add-on payment adjustment for that drug or biological product. As we noted earlier, if the latest available full calendar quarter of ASP data reflects zero or negative sales, CMS would calculate the post-TDAPA add-on payment adjustment based on WAC, or if WAC is not available, invoice pricing.

- Step 2, divide the total expenditure of the new renal dialysis drug or biological product from Step 1 by the total number of ESRD PPS treatments furnished during the same 12-month period as used in Step 1. The resulting

quotient from Step 2 would be the post-TDAPA add-on payment adjustment amount for each treatment, before applying the reduction factor to account for case-mix standardization, as described in Step 4.

- Step 3, calculate the dollar amount of the total aggregate case-mix adjusted post-TDAPA add-on payment adjustment amount by multiplying the post-TDAPA add-on payment adjustment amount from Step 2 by the applicable patient-level adjustments for each ESRD PPS treatment furnished during the 12-month period.

- Step 4, divide the aggregate case-mix adjusted add-on payment adjustment amount from Step 3 by total expenditure from Step 1. The resulting quotient would be the reduction factor applied to the post-TDAPA add-on payment adjustment amount to account for case-mix standardization.

- Step 5, apply the reduction factor from Step 4 to the post-TDAPA add-on payment adjustment amount from Step 2.

- Step 6, apply the 65 percent risk-sharing factor to the amount from Step 5 to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount.

- Step 7, multiply the case-mix adjusted post-TDAPA add-on payment adjustment amount by the ESRD PPS market basket update percentage.

We propose to amend 42 CFR 413.234 by revising § 413.234(c)(1)(i) and adding regulations at § 413.234(b)(1)(iii), (c)(1)(ii), (c)(3), and (g) that would describe the post-TDAPA payment adjustment and the calculation we would use to determine the post-TDAPA payment adjustment amount, as described above. In addition, we propose to amend § 413.230 by adding reference to the proposed post-TDAPA add-on payment adjustment in the calculation of the ESRD PPS per treatment payment amount.

In the section below, we provide an example of the proposed calculation for CY 2024 for *Korsuva*™ based on the latest available information at the time of this proposed rulemaking.

We are proposing to follow these steps to calculate the case-mix adjusted post-TDAPA add-on payment adjustment amount for CY 2024 and future years, when appropriate. We are proposing to include in the calculation of the case-mix adjusted post-TDAPA add-on payment adjustment amount any new renal dialysis drugs and biological products in existing ESRD PPS functional categories that are eligible for payment using the TDAPA described in § 413.234(c). We are proposing to begin making payment under this new post-

TDAPA add-on payment adjustment 8-calendar quarters after the beginning of the TDAPA payment period for the new renal dialysis drug or biological product. We are proposing that payment of the post-TDAPA add-on payment adjustment would end no later than 12 calendar quarters after the end of the TDAPA payment period for the new renal dialysis drug or biological product. We are soliciting comments on this proposed methodology for a post-TDAPA add-on payment adjustment and its appropriateness for CY 2024 and future years.

(b) Example of the Proposed Post-TDAPA Add-On Payment Adjustment Calculation

Following the proposed methodology in the previous section, we are proposing to apply a post-TDAPA add-on payment adjustment to all ESRD PPS treatments beginning April 1, 2024, when the TDAPA payment period for *Korsuva*™ ends. We are proposing to calculate the amount of this post-TDAPA add-on payment adjustment based on the most recent available 12 months of utilization data for *Korsuva*™ and the most recent available 12 months of ESRD PPS claims data for this proposed rulemaking. We are also proposing that we would use updated data, if available, for the ESRD PPS final rule. We are proposing to apply the ESRD PPS patient-level adjustment factors for determining the amount of the post-TDAPA add-on payment adjustment for each ESRD PPS claim.

Based on the latest available data, which includes utilization of *Korsuva*™ from May 2022 through December 2022, we estimate that total expenditure for *Korsuva*™ in CY 2022 is \$3,150,910 and that 19,511,284 total ESRD PPS treatments were furnished during the same time period. Taking into account the existing ESRD PPS patient-level adjustment factors and the proposed TPEAPA as discussed in section II.B.1.g of this proposed rule, the reduction to the post-TDAPA add on payment adjustment to account for case-mix standardization for this time period is 0.900244. Accordingly, we would calculate a proposed case-mix adjusted post-TDAPA add-on payment adjustment for CY 2024 equal to $((\$3,150,910)/(19,511,284)) \times (0.900244) \times (0.65) \times (1.017) = \$0.0961$. Estimates for the impact of this proposed post-TDAPA add-on payment adjustment for CY 2024 are included in section VIII.D.3 of this proposed rule.

(c) Considerations Related to Budget Neutrality for the Proposed Add-On Payment Adjustment

As discussed earlier in this proposed rule, the ESRD PPS includes other add-on payment adjustments based on the authority in section 1881(b)(14)(D)(iv) of the Act, which are not statutorily required to be budget neutral. In the case of existing add-on payment adjustments under the ESRD PPS, these generally account for costs that were not included in cost reports used for the construction of the ESRD PPS bundled payment. These include items that either did not exist at the time of the construction of the ESRD PPS bundled payment, like new drugs and equipment, or services that were not commonplace that the add-on payment adjustment is meant to encourage, like home dialysis training. We expect this increased payment would support ESRD facilities in providing the new renal dialysis drug or biological product to all beneficiaries for whom it is reasonable and medically necessary. We believe it is also important to support access to new renal dialysis drugs and biological products while minimizing the financial impact to beneficiaries, who incur a 20 percent coinsurance for renal dialysis services under the ESRD PPS.

As discussed above, we considered and are proposing this new post-TDAPA add-on payment adjustment in response to concerns that a sudden decrease in payment for certain new renal dialysis drugs and biological products after the end of the TDAPA period could negatively affect Medicare beneficiaries' access to such new renal dialysis drugs and biological products. Although we have noted that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, we do not believe that proposing a budget neutral payment adjustment would be appropriate for the post-TDAPA add-on payment adjustment. Because we are proposing to apply the post-TDAPA add-on payment adjustment to every ESRD PPS treatment, budget neutralizing this proposed add-on payment adjustment would effectively undo the adjustment and leave aggregate payments at the same level they would have been without an adjustment, which as we previously noted could negatively affect beneficiaries' access to such drugs and biological products. In contrast, applying this proposed add-on payment adjustment in a non-budget neutral manner would increase aggregate ESRD PPS expenditures to a level that reflects the most recent 12 months' utilization of

the new renal dialysis drug or biological product, which we believe would support beneficiary access. By applying the proposed post-TDAPA add-on payment adjustment in a non-budget neutral way, we would effectively maintain expenditures for these new renal dialysis drugs and biological products at 65 percent of the level of expenditures paid during the TDAPA period. We believe this approach would provide consistency and predictability in a way that would support beneficiaries' continued access to new renal dialysis drugs and biological products, while appropriately reducing expenditures for such drugs after the TDAPA period ends both for the Medicare program and for individual beneficiaries, as discussed earlier in this section. Accordingly, we are proposing that this post-TDAPA add-on payment adjustment would not be budget neutral. We welcome comments on the budget neutrality aspect of this proposal.

j. Proposal to Require "Time on Machine" Hemodialysis Treatment Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis

We are proposing certain new recordkeeping and cost reporting requirements for outpatient maintenance dialysis at proposed 42 CFR 413.198(b)(5). CMS proposes to require patient-level reporting on resource use involved in furnishing hemodialysis treatment in-center in ESRD facilities that would serve to apportion composite rate costs for use in the case-mix adjustment. Importantly, this new data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level, which would enable a refined single-equation estimation methodology. The integrity of the ESRD PPS is dependent on our ability to monitor payment accuracy and make refinements to the payment system, as needed. Under this proposal, CMS would require ESRD facilities to report information on ESRD PPS claims for renal dialysis services about the duration of time in minutes that ESRD beneficiaries spend in center receiving hemodialysis treatment, also known as "time on machine" (hereafter referred to in this section as "time on machine"). We would use time on machine data to help us evaluate and monitor the accuracy of our payments for patient-level adjustment factors. CMS would also evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which include

patient age, body mass index (BMI), BSA, and co-morbidities such as sickle cell anemia. Finally, CMS would review the data for its potential to identify any disparities from a health equity perspective that may support proposing in future rulemaking new patient-level adjustment factors, including potential social determinants of health (SDOH) factors.

(1) Statutory Authorities for Recordkeeping, Cost Reporting, and Case-Mix Adjustments Under the ESRD PPS

Section 1881(b)(2)(B) of the Act generally directs the Secretary to prescribe in regulations any methods and procedures to determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals with ESRD, and to determine, on a cost-related or other economical and equitable basis, payment amounts for Medicare part B services furnished by such providers and facilities to individuals with ESRD. To that end, CMS promulgated 42 CFR 413.198,³⁴ which specifies certain recordkeeping and cost reporting requirements for ESRD facilities that meet the conditions for coverage under 42 CFR part 494.³⁵ The recordkeeping and cost reporting requirements at § 413.198 enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis and support the two-equation payment model that is currently used as the basis for the ESRD PPS.

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. We implemented this statutory requirement in § 413.235, which sets forth certain patient characteristics for which the per treatment ESRD PPS base rate may be adjusted, specifically where those patient characteristics result in higher costs for ESRD facilities. The patient characteristics at § 413.235(a) include: patient age, body surface area, low body mass index, onset of renal

³⁴ We note that § 413.198 was promulgated prior to the establishment of the ESRD PPS. It was initially set forth in 1983 at 42 CFR 405.441 (48 FR 21254), to implement section 2145 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35). Section 405.441 was later redesignated in 1986 as 42 CFR 413.174 (51 FR 34790–01), and the requirements were moved again, from § 413.174 to § 413.198, in a reorganization of subpart H of part 413 (62 FR 43657).

³⁵ Likewise, under section 1881 of the Act, CMS established related data and information requirements at 42 CFR 494.180(h).

dialysis (new patient), and co-morbidities. The Secretary is also authorized, under section 1881(b)(14)(D)(iv) of the Act, to apply such other payment adjustments under the ESRD PPS as the Secretary determines appropriate. Per 42 CFR 413.196, we publish notice of any proposed changes to payment adjustments, including adjustments to the composite rate,³⁶ in the **Federal Register**. We last updated the payment multipliers for the ESRD PPS patient-level adjustment factors in the CY 2016 ESRD PPS final rule (80 FR 68968, at 68973 through 68984), for age, BSA, low BMI, sex, four co-morbidity categories (that is, pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis. We also established payment adjustments for pediatric patients and for facilities treating a low-volume of patients with ESRD.

Finally, the proposal to collect and evaluate time on machine data would provide additional information concerning resource use to enable CMS to identify, assess, and address potential health disparities. This proposal therefore may support the Secretary's efforts to evaluate race and ethnicity data and provide recommendations for improving the quality of the data, as required under section 1809 of the Act, previously discussed in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49108 through 49113).

We note that, if the proposed requirement to collect time on machine data were to be finalized as proposed, we would issue corresponding guidelines. Such guidance would provide instructions regarding the applicable administrative requirements for reporting a value code on an electronic claim, here value code D6, connected to the number of minutes of hemodialysis treatment provided in center in an ESRD facility. We further note that the National Uniform Billing Committee (NUBC) has approved and is prepared for ESRD facilities' use of value code D6 on claim form CMS-1450 (UB-04) (OMB-0938-0997), to report the total number of minutes of

hemodialysis provided during the billing period.

(2) Case-Mix Adjustments Background and the Two-Equation ESRD PPS Model

The ESRD PPS includes patient-level adjustments that adjust the ESRD PPS base rate for certain patient characteristics. The current ESRD PPS case-mix adjustments are derived from a case-mix adjustment model involving two equations. In the CY 2011 ESRD PPS final rule (75 FR 49083), we discussed the two-equation methodology used to develop the adjustment factors that would be applied to the ESRD PPS base rate to calculate each patient's case-mix adjusted payment per treatment. The two-equation approach used to develop the ESRD PPS included a facility-based regression model for services historically paid for under the composite rate as indicated in ESRD facility cost reports, and a patient-month-level regression model for services historically billed separately. One significant limitation, which in large part drove the development of the two-equation model, was that there was no way to reliably identify, using claims data, the costs for composite rate services—that is, items and services such as staff labor, dialysate, capital-related assets such as renal dialysis machines, and certain drugs and laboratory tests, that are used in the provision of outpatient maintenance dialysis for the treatment of ESRD and that were included in the composite payment system established under section 1881(b)(7) of the Act and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

In the CY 2016 ESRD PPS final rule, we updated the payment multipliers for the ESRD PPS patient-level adjustment factors for age, BSA, low BMI, sex, four co-morbidity categories (that is, pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis; we also established payment adjustments for pediatric patients and for ESRD facilities treating a low-volume of ESRD patients (80 FR 68968 at 68973 through 68984). In that CY 2016 ESRD PPS final rule, we discussed and responded to a number of public comments in which commenters expressed concerns about the continued use of the two-equation model (80 FR 68974 through 68976). One comment from MedPAC suggested that CMS develop a one-equation model for the ESRD PPS. In response, we noted that the ESRD PPS is not currently able

to utilize a one-equation method because ESRD facilities do not report charges associated with the components of renal dialysis treatment costs that vary across patients, such as time on machine. In other words, patient-level claims provide line item detail on the use of the formerly separately billable services, but do not provide any information regarding variation across patients in the use of the formerly composite rate services. In addition, we stated that we believed that capturing the resource cost for furnishing renal dialysis services is complex since Medicare has historically paid an ESRD PPS base rate (that is, composite rate payment) to account for those costs that were never itemized on a claim but were reported through the cost report (80 FR 68975 through 68976).

(3) Background on CMS Efforts To Explore the Use of "Time on Machine" Data To Refine the Case-Mix Adjustment Model

Interested parties, including MedPAC, have long expressed concerns about the complexity of the two-equation model underpinning the ESRD PPS and have questioned the validity of assuming that the composite rate costs for all patients at an ESRD facility are the same. Interested parties have encouraged CMS to develop a patient cost model that is based on a single patient-level cost variable that accounts for all composite rate and formerly separately billable services. Additionally, interested parties have expressed concerns that the existing case-mix adjusters might not correlate well with the current cost of renal dialysis treatment and have encouraged CMS to explore a refinement.

In response, CMS has explored the feasibility of collecting time on machine data on patient claims from ESRD facilities and the potential for using such data. These efforts include: a Technical Expert Panel (TEP) held on December 6, 2018, a Request for Information (RFI) published in the ESRD PPS CY 2020 ESRD PPS proposed rule (84 FR 38399), and more recently an RFI published in the ESRD PPS CY 2022 proposed rule (86 FR 36322, 36399 through 36400). In addition, CMS issued sub-regulatory guidance in Transmittal 10368, from September 24, 2020, in an effort to begin collecting time on machine data, but it later rescinded that guidance.

(a) Technical Expert Panel (TEP) December 2018

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), a TEP was held on

³⁶ As explained in the CY 2011 ESRD PPS final rule (75 FR 49030 at 49032), the composite rate is the method by which CMS determines prospectively the amounts of payments for renal dialysis services furnished by providers of services and by renal dialysis facilities to individuals in a facility, and to such individuals at home. The composite rate is a single composite weighted formula that is combined with separately billable services under a single payment, adjusted to reflect patient differences in resource needs or case-mix.

December 6, 2018, to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. In that CY 2020 ESRD PPS proposed rule, we discussed the purpose of the TEP and the topics that were discussed, including several data collection options.³⁷

In the CY 2020 ESRD PPS proposed rule, we noted that CMS's data contractor's pre-TEP analysis of CY 2016 cost report data showed that composite rate costs comprise nearly 90 percent of average total treatment costs, with capital, direct patient care labor, and administrative costs representing approximately 88 percent of total average composite rate cost per treatment. The data contractor provided examples of ways that longer duration of renal dialysis time might be associated with increased treatment costs, including utility costs, accelerated depreciation on equipment, and lower daily census counts, which, among other things, would result in increased per-treatment capital costs. The analysis suggested that additional labor hours for a patient with longer treatments on average could increase per-treatment labor costs, and that patients with increased use of dialysate and water treatment supplies or equipment likely have higher average per-treatment supply costs. We noted that, under current reporting practices, there are no data on the patient-and treatment-level variation in the cost of composite rate items and services. We explained that these findings underscore the importance of identifying variation in these costs to inform the development of a refined case-mix adjustment model.

CMS published the findings from the December 2018 TEP in a report dated June 2019.³⁸ The 2018 TEP report provided examples of ways that extended treatment duration could affect cost components. First, an imputed cost per treatment was calculated using a combination of treatment duration data from CROWNWeb³⁹ (now the ESRD Quality Reporting System, or EQRS) and facility

cost per-minute data from cost reports to infer differences in cost report costs across patient-months. An average interquartile range of 34.6 minutes was observed from CROWNWeb duration data, indicating significant within-facility variation in dialysis treatment time. Significant variation in average imputed cost per hemodialysis sessions also was observed, with an across-facility interquartile range of \$62.62. Overall, it was found that cost report costs increased with longer treatment times, and this pattern was consistent for the individual cost report components as well. Facilities with a higher proportion of beneficiaries receiving treatments ≥ 4.5 hours duration were found to have higher average costs for each cost component, with the exception of cost report drugs.⁴⁰

CMS presented further discussion into collection of time on machine data for each dialysis session in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), where we further identified this potential data set as a singular option that would provide sufficient data to develop a refined case-mix adjustment model. If renal dialysis session time were reported for each renal dialysis treatment, cost report and treatment-level data could be integrated to infer differences in composite rate costs across patients. In this paradigm, patient-level differences in composite rate costs could be attributed to two discrete categories: differences due to renal dialysis treatment duration (measured in units of time); and, differences unrelated to treatment duration. To alleviate concerns from interested parties, we noted that time on machine data would not be used to directly adjust ESRD PPS payment, rather, it would be used to apportion composite rate costs (currently only observable at the facility level to the patient or treatment level) for use in the case-mix adjustment. Time on machine data would allow for a higher proportion of composite rate costs to be allocated to patients with longer renal dialysis treatment times, and ultimately inform CMS refinements to existing patient-level adjusters, including age and comorbidities.

We further explained that, in the December 2018 TEP, the data contractor proposed two approaches to collect time on machine data: (1) Use existing data from Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb)

(now EQRS) on delivered renal dialysis minutes during the monthly session when a laboratory specimen is drawn to measure blood urea nitrogen (BUN); or (2) have ESRD facilities report time on machine data on Medicare claims. For the latter, we suggested that time on machine data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each renal dialysis treatment or by updating the definition of the existing revenue center code for renal dialysis treatments so that the units correspond to treatment time instead of the number of treatments. We noted that ESRD facilities already reported to CMS a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that ESRD facilities currently collect time on machine data.⁴¹ Moreover, we stated that we were aware that many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every renal dialysis treatment, minimizing additional burden of reporting this metric on claims.

The December 2018 TEP participants preferred that the data be collected on Medicare claims (84 FR 38398). They did not support using the then-existing CROWNWeb data for time on machine data, as there were too many questions about its completeness and timeliness. They agreed that if time on machine data is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments. We explained that the TEP participants cautioned that reporting time on renal dialysis on the claims would place additional burden on ESRD facilities. However, we stated that we believed that, for ESRD facilities with EHRs, the burden associated with the collection of renal dialysis treatment time is expected to be small and temporary, because the information is already being collected. We noted that collecting time on machine data could be difficult to accomplish for ESRD facilities that do not use EHRs. Lastly, we stated that some participants maintained that certain factors related to patient complexity—such as comorbidities and mental health status—that are associated with treatment costs are unrelated to treatment duration.

³⁷ The final TEP report from December 2018 and other materials can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

³⁸ The final TEP report from December 2018 is found directly at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf>.

³⁹ In 2008, CMS introduced an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) which was designed to collect clinical performance measures data from dialysis facilities (73 FR 20370, at 20372). CROWNweb is now "EQRS"—that is, the ESRD Quality Reporting System (OMB Control Number 0938–1289).

⁴⁰ Acumen LLC. ESRD PPS Case-Mix Adjustment Technical Expert Panel (TEP). Slide Presentation Slide 42. December 2018. See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf>.

⁴¹ Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Payment Year (PY) 2021 Measure Technical Specifications. Page 23. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2021-TechnicalSpecifications.pdf>.

(b) Request for Information (RFI) in the CY 2020 ESRD PPS Proposed Rule

In addition to presenting the findings from the December 2018 TEP, we solicited comments in the CY 2020 ESRD PPS proposed rule (84 FR 38399) on the option of collecting time on machine data. As discussed in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782), commenters responding to the RFI opposed the use of time on machine data, maintaining that other factors were more directly related to cost of treatment. Commenters claimed that many subgroups of patients are challenged to stay on renal dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs related to patients' special circumstances and comorbidities and not to treatment duration. With regard to patient-level factors contributing to high costs of care, commenters expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care and opposed the use of time on machine data as a single, patient-level factor to estimate variation in composite rate costs. Some commenters expressed the objection that use of this measure would not be productive because there was great homogeneity in treatment times across patients.

(c) CMS Sub-Regulatory Guidance in Transmittal 10368 (September 24, 2020) (Now Rescinded)

In Transmittal 10368, published September 24, 2020, CMS instructed its Medicare Administrative Contractors ("MACs") to implement a new value code D6, which reflects the total number of minutes of dialysis provided during the billing period. See Transmittal 10368, CR 11871 (*Changes to the End Stage Renal Disease (ESRD) PRICER to Accept the New Outpatient Provider Specific File Supplemental Wage Index Fields, the Network Reduction Calculation and New Value Code for Time on Machine*), effective January 1, 2021. At the same time, CMS announced a new requirement for ESRD facilities to report value code D6 on ESRD claims, for in-facility or home hemodialysis maintenance, training, or retraining treatments. Shortly after making these contractor directions public, CMS issued a Medicare Learning Network (MLN) Matters guidance document (MLN Matters No. MM11871) advising ESRD facilities of the new requirement to include treatment time on claims. However, after a large dialysis organization submitted a

petition⁴² pursuant to the HHS Good Guidance Practices Regulation,⁴³ HHS issued a finding that notice-and-comment rulemaking was required for CMS to impose such a requirement. Consequently, CMS rescinded Transmittal 10368 and replaced it with Transmittal 10576, dated January 20, 2021, withdrawing the requirement for reporting time on the dialysis machine with value code D6. Although the guidance to report time on machine data was rescinded, the value code D6 for the time on machine in minutes remains approved by the NUBC and remains on the CMS claim form CMS-1450 (UB-04) (OMB-0938-0997), in a deactivated status.

(d) Request for Information (RFI) in the CY 2022 ESRD PPS Proposed Rule

CMS revisited the topic of time on machine in the 2020 TEP and discussed the case-mix adjusters.⁴⁴ Interested parties continued expressing concerns that the existing case-mix adjusters might not align with resource-intensive patient-level services such as isolation rooms, behavioral issues, or neurocognitive issues. We sought additional public input in the ESRD PPS CY 2022 proposed rule, requesting information on the methodology used to calculate the case-mix adjustment (86 FR 36322, 36399 through 36400), in particular, the methodology to collect data to reflect patient-level differences in composite rate costs, including the use of a value code to collect time on machine on the claim.⁴⁵

We received similar comments on this RFI to those expressed in response to the CY 2020 ESRD PPS proposed rule. As discussed in the CY 2022 ESRD PPS final rule, commenters cited concerns that apportioned composite rate costs (such as labor and capital related costs) from the cost reports, used in the case-mix adjustments, were currently only observable at the facility-level and did

not include patient or treatment level variations.

Similar to previously mentioned concerns regarding the collection of time on machine data, commenters suggested this data element would be burdensome and complex (especially for those dialyzing at home), and would not identify high-cost patients. They stated that what little variation might be identified would not be worth the burden of collecting the information. In addition, these commenters stated that ESRD facilities' staffing is based on prescribed time, not on the actual time a patient is on the machine. They stated that the prescription approach is the most rational way to determine staffing levels, because ESRD facilities do not have time on machine in advance. According to these commenters, ESRD facilities thus would only have the prescribing physician's prescription to use.

A provider advocacy organization opposed the use of time on machine data for purposes of ESRD PPS primarily because certain patients benefit from shorter, more frequent dialysis, such as patients with catheter-related access issues, non-compliant patients, patients with chronic pain or diarrhea, and patients suffering from certain comorbidities. They expressed significant concern that use of time on machine data for differentiating treatment cost variability creates inappropriate incentives for certain ESRD facilities to "game the system" by: (1) putting patients on renal dialysis longer than necessary; or (2) placing patients on the cheapest dialyzer and keeping them on it for all five possible hours of dialysis. Another small renal dialysis organization agreed, pointing out that most renal dialysis treatments, regardless of time, will have similar composite rate costs. In other words, they asserted that if a treatment is 3.5 hours compared to 5 hours, the composite rate costs for those treatments will be very similar. The only difference in cost between those two treatments would be 1.5 hours more use of utilities, dialysate and bicarbonate solution, machine depreciation, and a small amount of labor to check on the patient. The vast majority of labor for renal dialysis treatments is putting the patient on and taking the patient off of dialysis. Therefore, in both of the above scenarios, the commenter asserted that cost will remain the same. Further, they pointed out that some patients will not remain for their full renal dialysis treatment, and they generally cannot force a patient to remain for their full prescribed treatment time. Therefore, in

⁴² The petition (dated December 23, 2020) is attached as Exhibit A to HHS's petition response (January 8, 2021) which can be found at <https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf>.

⁴³ The HHS "Good Guidance Practices" final rule appeared in the **Federal Register** on December 7, 2020 (85 FR 78770), and was later rescinded July 25, 2022 (87 FR 44002).

⁴⁴ <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>.

⁴⁵ We published a summary of the responses to the CY 2022 ESRD PPS RFI (86 FR 36322, 36399 through 36400) for the current case-mix methodology in the ESRD PPS CY 2022 final rule (86 FR 61874, 61997) and provided greater detail on the CMS website at <https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf>.

their view, using actual treatment time for cost allocation is not realistic.

A small renal dialysis organization within a large non-profit health system commented that reporting treatment times would be difficult and confusing and identified many factors that would need to be outlined by CMS including: When does renal dialysis time start; what happens when a patient chooses to discontinue their treatment early, or has complications resulting in reduced treatment time; what happens when an ESRD facility inadvertently does not track time for a treatment; how does this information get included on a claim; and how ESRD facilities would need to train staff on how to count and track time. They also expressed concern about the reporting of time on machine creating opportunities for ESRD facilities to game the system by having the renal dialysis run a few extra minutes to move into the next highest level.

Several commenters recommended changes or removal of the case-mix adjusters, including refinement of the age and weight (BSA and BMI) adjustments and removal of the comorbidity adjustments, based on declining frequency of claims containing comorbidities. Moreover, some comments recommended removal of the comorbidity adjustments, because they report the adjustments are not utilized. They recommended CMS refine the age and weight (BSA and BMI) adjusters to better capture and designate higher cost patients. Many commenters expressed the belief that the comorbidity categories no longer protect beneficiary access and no longer correlate with increased costs. A non-profit renal dialysis association recommended that CMS minimize resources devoted to adjusters, providing only the minimum needed to deliver quality patient care, restore significant funding to the ESRD PPS base rate for the benefit and care of all beneficiaries, and focus retained adjusters only on those that are clearly linked to patient cost of care or clear barriers to access. Specifically, they recommended that: CMS retire the remaining comorbid case mix adjusters; revise the weight adjusters to maintain a low-BMI adjuster; create a high-BMI adjuster; eliminate the BSA adjuster; retire the age adjuster (which they believe is not methodologically sound and does not resonate with clinician or renal dialysis facility experience of care); maintain the adjuster for low volume facilities; consider expanding the adjuster to a second tier of facilities providing fewer than 6,000 treatments per year; eliminate the rural adjuster;

and maintain the onset of renal dialysis adjuster to support the resource intensive needs of patients starting dialysis. Other commenters stated it would be too preliminary to eliminate the case-mix adjusters wholesale; they recommended that CMS initiate a discussion of the adjusters that are true drivers of high costs and how the use of adjusters can be operationalized for practical purposes. One payment adjustment that was universally supported by commenters was the onset adjustment.

MedPAC recommended that CMS develop a one-equation regression model in place of the current two-equation model currently used as the basis for the ESRD PPS. MedPAC also recommended that CMS consider removing the comorbidity adjustments and revise the body size adjustment. MedPAC further recommended that CMS address the inherent correlation between BSA and BMI by jointly estimating the association of BSA and BMI with treatment cost. Both BSA and BMI are calculated based on patient height and weight. MedPAC's analyses found that BSA and BMI values are correlated such that patients with low BMI also tend to have low BSA, and that these variables have a joint effect on treatment costs that is different from the sum of independent effects as currently implemented. We reiterated our current inability to implement such a model given the absence of data on the charges associated with the components of renal dialysis treatment costs that vary across patients in the use of the formerly composite rate services. A non-profit renal dialysis association agreed with MedPAC.

(4) Health Equity Considerations Supporting the Proposed Collection of Time on Machine Data

CMS prioritizes expansion of the collection, reporting, and analysis of standardized data as a key means to advance health equity.⁴⁶ By increasing our understanding of the needs of those we serve, CMS aims to ensure all individuals have access to equitable care and coverage. CMS's proposal to collect time on machine data supports these priorities. CMS believes the proposed data reporting requirements would support our ability to assess whether, and to what extent, our programs and policies may perpetuate or exacerbate systemic barriers to

opportunities and benefits for underserved communities.

As noted earlier, as part of CMS's December 2018 TEP and in the ESRD PPS CY 2020 final rule, CMS's EQRS data (formerly collected under CROWNWeb) is reported once per patient-month. Thus, CMS's proposal to collect time on machine data, which would require duration of treatment data reported for every renal dialysis treatment, would provide a more granular set of standardized data for analyzing (and, potentially, apportioning) composite rate costs for use in the case-mix adjustment. CMS would also look to time on machine data as a source to monitor claims data and identify disparities in care that could be mitigated by potential future adjustments that would incentivize equitable care within the framework of the ESRD PPS.

We note that ESRD PPS reform is an on-going multi-year effort to refine payment adjustments and methodologies under the ESRD PPS. Section 1881(b)(2)(B) of the Act provides that the Secretary shall prescribe in regulations any methods and procedures to determine the amounts of payments to be made for part B services (which include renal dialysis services), on a cost-related basis or other economical and equitable basis. Furthermore, section 1881(b)(14)(D) of the Act requires the ESRD PPS to include a payment adjustment based on case mix that may take into account various patient characteristics and other appropriate factors.

Since the establishment of the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030), CMS has been engaged in ongoing monitoring and analysis of the ESRD PPS. CMS publishes these monitoring results regularly.⁴⁷ CMS's monitoring activities have involved analysis of ESRD facility cost reports and patient claims to determine the most accurate adjustments and methodologies as well as to identify trends in beneficiary health outcomes. Similarly, CMS notes that this proposal to collect more-detailed standardized data (that is, the proposed time on machine reporting) than is presently available for analysis supports our ability to evaluate potential disparities in health care provided to our beneficiaries.

⁴⁷ Since the implementation of the ESRD PPS in January 2011, CMS has monitored outcomes, through a claims-based monitoring program, for Medicare beneficiaries receiving outpatient maintenance dialysis. See <https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/esrd-claims-based-monitoring>.

⁴⁶ <https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity>.

Presently, CMS adjusts the per-treatment ESRD PPS base rates to account for variation in the case mix, as set forth in 42 CFR 413.235. These adjustments account for patient age, BSA, low BMI, onset of renal dialysis (new patient), and comorbidities (for example, sickle cell anemia), as specified by CMS. The data and information that inform these adjustments are derived from cost reports, which are submitted to CMS on the facility level. However, we note that time on machine data would be provided to CMS at the patient level, on patient claims. This change would shift CMS's focus to a more patient-centered paradigm. We believe time on machine data would provide the insights we need to develop (and propose) potential amendments to the payment multipliers for the current, and potential future, patient-level adjustments, including new SDOH factors or health conditions (such as profound post-dialytic exhaustion) as patient-level adjustments. More immediately, however, time on machine data would significantly enhance CMS's insight into whether our current payment adjusters are appropriately aligning with actual resource use for individuals and communities who are underserved or disadvantaged and who may have multiple patient-level characteristics that necessitate longer renal dialysis times.

For example, CMS is aware of anecdotal evidence and published studies showing that patients with the comorbidity of sickle cell anemia may need a longer renal dialysis treatment time as well as additional resources from medical staff to attend to the manifestations of sickle cell that occur during dialysis. In fact, renal dialysis patients with sickle cell anemia may have frequent pain attacks during the actual renal dialysis treatment.⁴⁸ Such an attack, known as a vaso-occlusive pain crisis, precipitates a series of medical interventions involving intravenous fluids, analgesia, as well as the treatment of any precipitant and/or acute comorbid state.⁴⁹ CMS would be able to use time on machine data for patients with sickle cell anemia to evaluate its alignment with the patient-

level adjuster for the corresponding comorbidity.

In addition to re-evaluating and potentially updating the payment multiplier for the patient-level adjuster for the co-morbidity of sickle cell anemia, CMS anticipates that there could be other instances where patients need more time on renal dialysis to avoid uncomfortable post-dialytic sequela, such as profound post-dialytic exhaustion. In instances of profound post-dialytic exhaustion, for example, CMS would evaluate the forthcoming time on machine data for the potential correlations between additional hemodialysis treatment time and decreased incidence of profound post-dialytic exhaustions, which may have cost implications. We are aware that there may be a need for a future patient-level payment adjuster associated with post-dialysis fatigue.

(5) Proposed Requirement for Reporting Time on Machine Data To Evaluate Accuracy of Current Payment Adjusters Aligned With Resource Use

We propose to require patient-level reporting on resource use involved (time on machine) in furnishing hemodialysis treatment in-center in ESRD facilities, which would serve as a proxy to apportion composite rate costs (capital, labor, and administrative costs, as well as drugs, laboratory tests, and supplies necessary to administer the dialysis treatment) for use in the case-mix adjustment. This would allow us to more precisely estimate the average costs of the various above-mentioned components of a renal dialysis treatment that cannot currently be captured because payment for these items is bundled, and claims data do not contain detail on the use of these items and services. CMS would review the patient-level resource use data, including time on machine data, to evaluate and monitor the accuracy of the methods and procedures, including the patient-level adjustment factors, enhancing the integrity of the ESRD PPS. In addition, CMS would evaluate whether the data could be used to inform future refinements to the existing patient-level adjustment factors set forth at § 413.235(a), which may include age, BMI, BSA, and co-morbidities such as sickle cell anemia. Finally, CMS would review the data for its potential to identify any disparities from a health equity perspective and to support the future proposal of any new patient-level adjustment factors, including potential SDOH factors. We note that such data may also be used to inform potential future refinements to the facility-level adjustment factors, if appropriate. Per

42 CFR 413.196, we would publish notice of any proposed changes to payment adjustments, including adjustments to the composite rate, in the **Federal Register**.

(a) Proposed Changes to 42 CFR 413.198

We propose to amend 42 CFR 413.198 by adding language at § 413.198(b)(5) that would require each ESRD facility to submit data and information, under existing paragraph § 413.198(b)(3) describing allowable costs, of the types and in the formats established by CMS, for the purpose of estimating patient-level and facility-level variation in resource use, such as data and information on the duration of hemodialysis treatment (that is, time on machine data) involved in furnishing hemodialysis treatment in center in an ESRD facility. For additional context, we note that, under § 413.198(b)(3), allowable cost is the reasonable cost related to renal dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the ESRD facility in furnishing the renal dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. Reasonable cost includes both direct and indirect costs and normal standby costs.

We also propose to update § 413.198(a) by adding a reference to section 1881(b)(14) of the Act to acknowledge the statutory provisions for the ESRD PPS.

(b) Additional Considerations for the Proposed Reporting of Time on Machine Data CMS reviewed past comments from its TEPs and RFIs and gave additional consideration to the approach of our now-rescinded sub-regulatory guidance in Transmittal 10368 and to the complexities of reporting the number of minutes of hemodialysis treatment on patient claims. With this background in mind, we further refined our proposed requirements at proposed § 413.198(b)(5) in a way that would result in the reporting of the most useful, high value data.

In light of past comments questioning the feasibility and accuracy of time on machine reporting for home dialysis patients, we are proposing a reporting requirement that would only apply to patients receiving an in-center hemodialysis treatment. We believe this approach would ensure greater uniformity to the recording process and thus greater consistency in the data reported. We note that Chapter 11 of the Medicare Benefit Policy Manual at

⁴⁸ Benjamin Jacob et al. Management of the Dialysis Patient with Sickle Cell Disease (Seminars in Dialysis 14 July 2015, <https://doi.org/10.1111/sdi.12403>).

⁴⁹ Derebail VK, Lacson EK Jr, Kshirsagar AV, Key NS, Hogan SL, Hakim RM, et al.: Sickle trait in African-American hemodialysis patients and higher erythropoiesis-stimulating agent dose. *J Am Soc Nephrol* 25: 819–826, 2014.

section 10.A.1,⁵⁰ defines “hemodialysis” as the process by which blood passes through an artificial kidney machine and the waste products diffuse across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient’s body. Hemodialysis is accomplished usually in 3 to 5 hour sessions, 3 times a week.

CMS also considered past comments responding to its RFI in the CY 2020 ESRD PPS final rule (84 FR 60648, 60782) regarding patient-level factors that contribute to high costs of care. CMS agrees with commenters that expressed that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care.

We also considered comments from a provider advocacy organization that opposed the use of time on machine data for purposes of ESRD PPS primarily because, they stated, certain patients benefit from shorter, more frequent dialysis, such as patients with catheter-related access issues, non-compliant patients, patients with chronic pain or diarrhea, and patients suffering from certain comorbidities. Still other commenters claimed that many subgroups of patients are challenged to stay on renal dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs related to patients’ special circumstances and comorbidities and not to treatment duration. The commenters noted that, in both of the above scenarios, costs would remain the same. Further, they pointed out that some patients will not remain for their full renal dialysis treatment, and short of using restraints, there is nothing that can be done to force a patient to remain for their full prescribed treatment time. Therefore, in their view, using actual treatment time for cost allocation is not realistic.

CMS agrees that the payment multipliers for patient-level adjusters should be grounded in strong evidence, and we recognize that each patient will have unique needs, with some being more costly to treat and others with fewer costs, given their medical backgrounds. We emphasize and again clarify that, under this proposal, time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments.

CMS also considered comments suggesting that a “time on machine” data element would not identify high-cost patients and comments suggesting such a data element would not be productive given the commenter’s assertion that there was great homogeneity in treatment times across patients. One commenter noted that the vast majority of labor for renal dialysis treatments is putting the patient on and taking the patient off of dialysis, and another commenter pointed out that most renal dialysis treatments, regardless of time, will have similar composite rate costs. (In other words, they asserted that if a treatment is 3.5 hours compared to 5 hours, the composite rate costs for those treatments will be very similar. The only difference in cost between those two treatments would be 1.5 hours more use of utilities, dialysate and bicarbonate solution, machine depreciation, and a small amount of labor to check on the patient.) We agree with commenters that treatment times and costs may be similar across most patients based on our analysis and the comments of TEP participants. However, we would not expect to find that ESRD facilities are treating ESRD patients in a homogeneous fashion, but on a case-by-case basis determined by patient-centered plans of care. We note that a review of CY 2016 cost report data, conducted as part of the December 2018 TEP,⁵¹ showed that overall costs of renal dialysis services (within the ESRD facility cost reports) increased with longer treatment times, and that this pattern was consistent for the individual cost report components.

We anticipate that the data that would become available under the proposed requirement, if finalized, for reporting time on machine data would provide insight into meaningful, measurable variabilities in certain costs associated with patient-level characteristics.

The significance of the proposed time on machine data is dependent upon the collection of data from a preponderance of patient claims for in-facility hemodialysis. While the majority of patient claims may come from patients with similar profiles and treatment plans, the needs of the more complex and resource-intensive patients can only be identified by CMS through the collection of patient-level data from across the ESRD PPS patient population.

Complex and resource-intensive patients are frequently encountered in the ESRD dialysis treatment setting, but it is not possible to obtain precise estimates of the higher costs of these patients’ hemodialysis treatments from currently reported data. Cost reports and claims are the two data sources from which per treatment costs can be estimated. Since cost reports aggregate data at the facility level, patient-level differences in resource use are not detectable as higher medical needs, and related costs are masked by averages. Further, analysis of claims data from 2016 found that roughly 99 percent of ESRD facilities reported 10 or fewer distinct charge values across all patients and treatment modalities.⁵² Routinely collected, ESRD patient population-based data on time on machine for each in-facility hemodialysis treatment would enable CMS to assess variation in the use of composite rate items and services at the patient level and to identify high-need and high-cost patients. In addition, the proposed time on machine data set would enable CMS to further determine what trends or causal relationships may exist between certain patient-level characteristics and the number of minutes of hemodialysis treatment received by such patients. CMS would evaluate whether specific patient characteristics are associated with increased length of dialysis treatment, which contribute to cost.

We also considered comments that the costs to ESRD facilities for providing dialysis treatment could be better measured by looking at costs based on prescribed time, and not on the actual time a patient is on the dialysis machine. The commenters stated their view that looking to prescribed time(s) would be the most rational way to determine staffing levels (and costs), because ESRD facilities plan for dialysis session length based on the prescribed time. Although CMS recognizes ESRD facilities’ labor practices to align staffing with the stated prescription times, CMS is concerned that, for some patients, their prescription times are not aligning with actual usage and thus may not be the best predictor of ESRD facilities’ costs. For example, we are aware that patients who experience severe itching

⁵⁰ Section 10.A.1 of Chapter 11 of the Medicare Benefit Policy Manual also directs the reader to review section 50.A.1 of Chapter 11 for payment information.

⁵¹ As presented on Slide 42 from the December 2018 TEP, overall costs of renal dialysis services (within the ESRD facility cost reports) increased with longer treatment times. See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf>.

⁵² See page 9 of the December 2018 TEP Report at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Summary-Report-June-2019.pdf>. See also Slide 27 from the December 2018 TEP Presentation at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/ESRD-PPS-TEP-Presentation.pdf>. And see Slide 30 from the December 2019 TEP Presentation at <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2019.pdf>.

or have certain psychological disorders may be less likely to receive dialysis for the full prescribed time. For such patients, only the collection of time on machine data for the number of minutes of hemodialysis treatment received would facilitate CMS's understanding of their complex needs and the implications for the ESRD PPS. For such patients, a pattern of shorter treatment times may ultimately result in worse patient outcomes and higher patient costs to the ESRD facility as well as to Medicare. CMS is also aware that patients with certain characteristics, such as higher BSA quartiles, may be more likely to need longer dialysis times.⁵³ Additionally, CMS has been made aware of instances in which ESRD facilities may avoid treating complex patients or patients with higher costs generally (thereby favoring average or lower cost patients). We note that prescribed dialysis times would not provide insight into costs for dialysis sessions for patients whose individual needs or circumstances might necessitate a dialysis treatment time that differs in practice from the prescribed dialysis time. Therefore, identifying actual resource usage, as correlated with the needs, health outcomes, and patient-level characteristics of complex patients would enable CMS to better align the payment multipliers with resource use within the ESRD PPS.

We anticipate that our proposed requirement would generate the data we would need to evaluate a potential adjustment of the payment multipliers for patient level adjustments, thereby allowing us to counteract possible financial disincentives to serving those patients. We would expect that such adjustments may thereby enhance access to renal dialysis services for such resource-intensive patients. We also believe that collecting time on machine data is preferable to collecting prescribed times, since we recognize that patients' actual experiences do not always align with their doctors' orders.

Finally, we considered the comments by a small renal dialysis organization within a large non-profit health system that reporting treatment times would be difficult and confusing and that identified many factors that would need to be outlined by CMS including: When does renal dialysis time start; what happens when a patient chooses to discontinue their treatment early, or has complications resulting in reduced treatment time; what happens when an

ESRD facility inadvertently does not track time for a treatment; how does this information get included on a claim. We recognize that a new reporting requirement will require uniformity in its implementation across ESRD facilities. We note that the proposed "time on machine" requirement is for the reporting of the number of minutes of hemodialysis treatment a beneficiary receives, and it refers to only the minutes (reported in whole minutes) spent dialyzing, while the patient is connected to the dialysis machine. If the proposed requirement were to be finalized, we would address such details in operational guidance.

(c) Using a Medicare Claims Data Field to Report Time on Machine Data

We propose that ESRD facilities report the number of minutes of hemodialysis treatment received in center in an ESRD facility using the D6 value code on the Medicare 72X type of bill (TOB) that is part of the CMS claim form CMS-1450 (UB-04) (OMB-0938-0997).⁵⁴ While our proposal limits the time on machine reporting requirement to in-center claims, to address the concerns raised by interested parties about the burden and complexity of home dialysis reporting, we note that time on machine for home dialysis data could nonetheless be voluntarily reported using the D6 value code on claims.

CMS further notes that the proposed time on machine data requirement would be collected on Medicare 72X claims. This approach would address long-standing concerns, including such concerns raised by MedPAC and other interested parties, that CMS should move to a one-equation model. CMS agrees with interested parties that a single-equation model, to be constructed at the patient level, would reduce the complexity of the current model and would better align payment with costs. The current two-equation model's payment adjusters are derived using

weighted averages of the coefficients from the facility-level and patient-level equations. Because the composite rate items currently compose roughly 90 percent of the payment, we are seeking a more detailed understanding of patients' utilization of such treatment resources. We anticipate that the time on machine data would provide a useful proxy for these composite rate items.

Furthermore, CMS notes that its proposal to collect time on machine data on patient claims would address past comments on whether such a reporting requirement could create perverse incentives for ESRD facilities to amend actual reported time on machine. Another past commenter expressed concern about whether an ESRD facility might have the renal dialysis run a few extra minutes to increase the payment. However, we note that requiring the reporting of time on machine data on a claim, by definition, would involve an attestation that the information submitted is correct and that the items presented represent medically necessary expenses. The False Claims Act (31 U.S.C. 3729 to 3733) establishes civil liability for knowingly presenting a false or fraudulent claim to the government for payment.

We note that, if the proposed requirement to collect duration of treatment data were to be finalized, we would then issue operational guidance in support of the requirement. Such guidance would describe the applicable instructions for reporting a value code (in this case, the D6⁵⁵ value code) connected to the number of minutes of hemodialysis treatment provided to a patient in center.

(d) Proposed Use of Time on Machine Data for the ESRD PPS

We emphasize and again clarify that, under this proposal, time on machine data would not be directly used to determine payment for renal dialysis services, nor would higher payments be made for longer treatments. Rather, time on machine data would allow for patient-specific calculation of costs for composite rate services, including labor costs, costs for the use of renal dialysis machines and related equipment, and costs for such items as dialysate and other essential supplies. In this way, time on machine data would be used to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month

⁵³ See slide 31 from the 2020 ESRD TEP presentation, which can be found here: <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf>.

⁵⁴ We considered collecting relevant time on machine duration of treatment data through the ESRD Quality Reporting System (EQRS), but we did not propose this approach due to concerns that interested parties raised—which we discussed in the December 2018 TEP and in the ESRD PPS CY 2020 final rule—that CROWNWeb (now EQRS) data is not reflective of typical patient treatment duration throughout the month. We note that EQRS data is reported once per patient-month and thus would include fewer observations than duration of treatment data reported for every renal dialysis treatment. It could therefore be less reliable for the purposes of monitoring and evaluating patient-level resource use, as well as for the purposes of apportioning composite rate costs for use in the case-mix adjustment. We further note that EQRS data are submitted on a voluntary basis and reflect a point in time each month for each facility and thus do not capture the full range of variation that ESRD facilities experience with patients over time.

⁵⁵ Value code D6 on claim form CMS-1450 (UB-04) (OMB-0938-0997), for reporting the total number of minutes of dialysis provided during the billing period.

level, which would enable a refined, single-equation estimation methodology. The refined, single-equation regression analysis (currently under development) would still be used to determine the inclusion/exclusion and magnitude of payment multipliers for patient-level case-mix flags that are associated with higher costs. Final payment adjustments would still only depend on existing patient-level case-mix adjusters, rather than a factor directly derived from time on machine data.

(e) Request for Information About Effective Date

We are proposing a January 1, 2025, effective date for this new reporting requirement. We are aware that all ESRD facilities record the time a patient has received hemodialysis treatment into a patient's medical record, and that, for most ESRD facilities, this time is automatically recorded into the patient's electronic health record (EHR). We further understand that ESRD facilities are able to transfer data from EHRs into the patient-specific claims that are submitted to Medicare for payment. However, we recognize that some ESRD facilities with limited resources may need to make modifications to their record keeping and reporting systems to facilitate the transfer of a patient's recorded hemodialysis treatment time in the patient's medical record to the Medicare claim. Although we did receive a past comment indicating that a facility's implementation time would involve training staff on how to count and track time, we do not expect that the manual recording of a patient's hemodialysis treatment time into their health record is widespread. Finally, we note that ESRD facilities are already reporting extensive information from patient EHRs into Medicare institutional claim form CMS-1450 (UB-04) (OMB-0938-0997), and we would not expect implementation to be overly burdensome to ESRD facilities. We recognize that some ESRD facilities would need to establish a new pathway from patient EHRs to the Medicare claim form, in addition to making simpler programming updates to add a field for the total number of minutes of dialysis provided during the billing period. Based on our findings in the TEP from December 2018, we anticipate that the implementation challenges that ESRD facilities might experience would be small and temporary, as a patient's time receiving dialysis treatment is already collected for the patient's medical record. We are seeking comment on whether an earlier effective date, such as January 1, 2024, is feasible

and would provide ESRD facilities with adequate time to implement this new reporting requirement.

(6) Proposed Technical Change to 42 CFR 413.198

We are proposing to fix a typographical error in 42 CFR 413.198(b)(3)(iii), which currently refers to "luxury items or services". We are proposing to change this to "luxury items or services".

k. Proposed Clarification to TDAPA Average Sales Price (ASP) Policy

In the CY 2020 ESRD PPS final rule, we finalized a conditional policy for TDAPA payment based on the availability of ASP data (84 FR 60679). In that final rule, we explained that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on WAC or invoice pricing, we believed we would be overpaying for the TDAPA for those products. We stated that we would no longer apply the TDAPA for a new renal dialysis drug or biological product if a drug manufacturer submits a full calendar quarter of ASP data into CMS within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product, but at a later point during the applicable TDAPA period specified in § 413.234(c)(1) or (2), stops submitting a full calendar quarter of ASP data into CMS. We explained that once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters. For example, we stated that if we begin paying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after the close of the 3rd quarter of paying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of paying the TDAPA), we would stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of paying the TDAPA).

We adopted this conditional policy in order to avoid overpaying for the TDAPA on an ongoing basis and in order to ensure that TDAPA payment is based on the most appropriate data, that is, ASP. Specifically, we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38349) and final rule (84 FR 60680) that we were concerned about (1)

increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS.

Our existing regulation at § 413.234(c) does not specifically address the application of the TDAPA conditional policy in situations in which the manufacturer of the new renal dialysis drug or biological product submitted ASP data to CMS and reported zero or negative sales. Zero or negative sales may occur for a variety of reasons, including no sales, recalls of a product, or repurchases of sold products. In the CY 2012 PFS final rule (76 FR 73296), CMS clarified that zero or negative values are valid for ASP, ASP units, and WAC. Therefore, when such a scenario occurs for separately payable Part B drugs, we consider the submission of zero or negative sales to fulfill the reporting requirements of manufacturer ASP data to CMS as set forth in sections 1927(b)(3)(A)(iii) and 1847A(f) of the Act. We note that in situations when zero sales are submitted, CMS guidance⁵⁶ instructs the manufacturer to report "0.000" for the ASP and the number of ASP units. The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based either on the published WAC or invoice pricing (except under OPPS, where the payment allowance limit is 95 percent of the published average wholesale price (AWP)). In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication 100-04, Chapter 17, section 20.4 Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC.⁵⁷ Therefore, for purposes of the TDAPA conditional policy, in circumstances where a manufacturer submitted ASP data reflecting zero or negative sales during the TDAPA period, we are

⁵⁶ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP_Data_Collection_Validation_Macro_User_Guide.pdf.

⁵⁷ Medicare Claims Processing Manual Chapter 17, section 20.1.3 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>.

clarifying that we consider CMS to have received the latest full calendar quarter of ASP data, and we would not discontinue TDAPA payment under the conditional policy in § 413.234(c). Consistent with the pricing methodologies for separately payable Part B drugs, we would set the TDAPA payment amount based on WAC, or if WAC is not available, invoice pricing, for the quarter in which zero or negative sales were reported.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Proposals and Application for CY 2024 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we would provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the FDA on or after January 1, 2020; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular CY; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at § 412.87(b)(1) and related guidance; and (6) is not a capital-related asset that an ESRD facility has an economic interest in

through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we would use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; an

improved quality of life; or (6) a demonstrated greater medication adherence or compliance; or,

- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payment adjustments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and ESRD facility settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. We would consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual

ESRD PPS proposed rules. Then, after consideration of public comments, we would announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular CY. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular CY. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for certain new and innovative renal dialysis equipment or supplies. We stated that the TPNIES is paid for two calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236(e) that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular CY to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY. In addition, a copy of the applicable FDA marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for

biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criteria, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID-19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for

all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In accordance with § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular CY, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular CY. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.⁵⁸ We finalized that this amount would be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in

⁵⁸ The CY 2023 TPNIES offset amount was \$9.79. CMS is proposing a CY 2024 TPNIES offset amount of \$9.96, as discussed in section II.B.1.e of this proposed rule.

which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines.

2. Proposed Clarifications Regarding CMS's Evaluation of the TPNIES Eligibility Criteria

This section of the proposed rule discusses proposed clarifications to our policies for evaluating the TPNIES eligibility criteria under § 413.236(b).

a. Sequential Order of CMS Review of the TPNIES Eligibility Criteria (§ 413.236(b))

As stated previously, we consider whether a new renal dialysis supply or equipment meets the TPNIES eligibility criteria as part of the annual ESRD PPS rulemaking and announce the results in ESRD PPS final rule. To qualify for the TPNIES, an applicant must meet each of the TPNIES eligibility criteria set forth in § 413.236(b)(1) through (6). An applicant that fails to demonstrate that it meets each of the six eligibility criteria is not eligible for the TPNIES.

In the CY 2021 ESRD PPS final rule, we focused our analysis of the TPNIES eligibility criteria on those that were not met. That is, for the TheraNova Dialyzer, we included our analysis of how the applicant did not meet the innovation criterion under § 413.236(b)(5), and for the Tablo® cartridge, we included our analysis of how the applicant did not meet the newness criterion under § 413.236(b)(2) and innovation criterion under § 413.236(b)(5) (85 FR 71444 through 71464). In the CY 2022 and CY 2023 ESRD PPS final rules, we expanded our analysis to include our determination as to whether the applicants met each of the six criteria. In doing so, we analyzed the TPNIES eligibility criteria in the sequence that is provided in § 413.236(b)(1) through (6) (86 FR 61889 through 61906 and 87 FR 67193 through 67216).

We clarify that our analysis of the TPNIES eligibility criteria would continue to proceed in sequential order. Specifically, in the annual ESRD PPS proposed rule, we would continue to summarize the information from the application regarding each of the six eligibility criteria and include any

questions or concerns that we identify during our analysis of the application.

Based on information provided by the applicant and from public comments during the annual ESRD PPS rulemaking cycle, we would continue to analyze the TPNIES eligibility criteria in sequential order in the annual ESRD PPS final rule. However, the change that we are proposing is that once it has been established that one criterion has not been met, we would not discuss or make specific determinations on the subsequent criteria for that item in the annual ESRD PPS final rule. We note that the criteria set forth in § 413.236(b) are intentionally listed in the order in which they appear. The first criterion is foundational in that an equipment or supply that is not a renal dialysis service would not be paid for under the ESRD PPS and therefore would not fit within the TPNIES payment pathway. As such, it would not be pertinent to evaluate the remaining TPNIES criteria for that item. TPNIES criteria two through four are objective and not subject to interpretation in that they each require date evidence to demonstrate newness, commercial availability, and the submission of a HCPCS application, respectively. The TPNIES innovation criterion under § 413.236(b)(5) requires the most significant CMS evaluation. Under our TPNIES policy and § 412.87(b)(1)(i), CMS is required to consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. In doing so, we consider various non-objective circumstances in our review of the TPNIES applications, including the state of the ESRD landscape and the particular challenges and vulnerabilities of patients with ESRD (86 FR 61905). We believe that it is prudent to reserve our in-depth analysis of the TPNIES innovation criterion only for applications that provide the necessary evidence to demonstrate that they meet the earlier foundational and objective TPNIES criteria.

As described previously in the background section of this proposed rule, the TPNIES innovation criterion in § 413.236(b)(5) incorporates the substantial clinical improvement criteria in the IPPS regulations at § 412.87(b)(1) for the new technology add-on payment (NTAP). This sequential approach for reviewing eligibility criteria is also in place for the NTAP pathway. The FY 2009 IPPS final rule (73 FR 48561 through 48563)

discussed the way in which CMS evaluates the NTAP eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. The NTAP cost criterion is not applicable in analyzing TPNIES eligibility. However, consistent with our approach under NTAP, we believe that the most prudent use of CMS resources would be to reserve our analysis and determination regarding whether a new equipment or supply meets the TPNIES innovation criterion by representing a substantial clinical improvement over existing technologies until after we determine the new equipment or supply meets the earlier criteria.

Under this proposal, we would first determine whether an equipment or supply meets the renal dialysis service criterion in § 413.236(b)(1) and present our analysis of this first criterion in the final rule. In instances where CMS determines that § 413.236(b)(1) has been met, we would proceed in assessing the newness criterion in § 413.236(b)(2) and present our analysis of this second criterion in the final rule. In instances where CMS determines that § 413.236(b)(2) has been met, we would proceed in assessing whether the commercial availability criterion in § 413.236(b)(3) has either been met or the applicant expects that it will be met by January 1 of the particular calendar year deadline and present our analysis of this third criterion in the final rule. In instances where CMS determines that § 413.236(b)(3) has been met or the applicant expects that it will be met by January 1 of the particular calendar year deadline, we would proceed in assessing the HCPCS Level II code application criterion in § 413.236(b)(4) and present our analysis of this fourth criterion in the final rule. In instances where CMS determines that § 413.236(b)(4) has been met, we would proceed in assessing the innovation criteria in §§ 413.236(b)(5) and 412.87(b)(1) and present our analysis of this fifth criterion in the final rule. In instances where CMS determines that § 413.236(b)(5) has been met, we would proceed in assessing the non-capital-related asset (except home dialysis machines) criterion in § 413.236(b)(6) and present our analysis of this sixth criterion in the final rule. In instances where CMS determines that

§ 413.236(b)(6), as well as each of the five preceding criteria in § 413.236(b)(1) through (5) as discussed above have been met, the equipment or supply would qualify for and would be paid for under the ESRD PPS using the TPNIES per § 413.236(d) beginning in the year that is the subject of the rulemaking.

In summary, we are proposing to clarify that as CMS proceeds through the sequential analysis of the six TPNIES eligibility criteria in the ESRD PPS final rule for a particular equipment or supply, once we determine that the item has failed to demonstrate having met one of the eligibility criteria, the item would be ineligible for the TPNIES. We would limit our analysis in the final rule to the TPNIES criterion that is not met and any preceding criteria that have been determined to have been met. We would not include the analysis of the remaining criteria in the final rule. If finalized, this policy would be effective January 1, 2024, and would apply to our analysis of TPNIES applications for CY 2025 payment.

b. Clarifications Regarding the TPNIES Newness Criterion (§ 413.236(b)(2))

As stated previously, applicants must meet the newness criterion in § 413.236(b)(2) to qualify for the TPNIES. CMS defines the TPNIES newness criterion at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. In this proposed rule, we wish to clarify two distinct aspects of the criterion that are consistent with our current TPNIES policies and would not represent any changes to the eligibility criteria: (1) the 3-year newness period and (2) FDA marketing authorization.

First, with respect to the 3-year newness period, we stated in the CY 2021 ESRD PPS final rule that by defining new as within 3 years beginning on the date of the FDA marketing authorization, we limit eligibility for the TPNIES to new technologies but allow prospective TPNIES applicants 3 years beginning on the date of FDA marketing authorization in which to submit their applications (85 FR 71410 through 71464).

To ensure that the timeframe during which a prospective TPNIES applicant is eligible to apply is clear, we are proposing to modify our regulation to specify that the applicant would have 3 years from the date of FDA marketing authorization to apply for the TPNIES, based on the date the application is submitted. This proposed modification is consistent with current policy, and while it is not a change in policy, we believe that clarifying the regulation text would help to eliminate any confusion

about the 3-year newness period. As indicated in § 413.236(c), February 1 prior to the particular calendar year is the annual TPNIES application submission deadline. We are proposing to clarify that the 3-year newness period is only for submission of the complete application. An applicant does not have to ensure that the application is submitted and that CMS renders its determination through notice and comment rulemaking within the 3-year newness period. Specifically, we are proposing to revise § 413.236(b)(2) to clarify that the equipment or supply is new if a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization.

Second, with respect to the requirement in § 413.236(b)(2) that the equipment or supply must have FDA marketing authorization, we clarify that an equipment or supply with FDA Exempt status would not meet the newness criterion and therefore would not be eligible for the TPNIES. As described on the FDA website, the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act established three regulatory classes for medical devices: Class I, Class II, and Class III. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective.⁵⁹ Most Class I and some Class II devices, as noted on FDA's website, are exempt from premarket notification (510(k)) requirements, subject to certain limitations.⁶⁰ As we stated in the CY 2023 ESRD PPS final rule, devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and effectiveness for the devices. For exempt devices, FDA has determined that a premarket notification is not required to provide a reasonable assurance of safety and effectiveness for the devices. However, generally a Class I or Class II device that is exempt from 510(k) requirements still must comply with certain regulatory controls (known as "general controls") to provide a reasonable assurance of safety and effectiveness for such devices. In limiting the TPNIES policy to items that have received FDA marketing authorization, we intended to exclude

⁵⁹ Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: <https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing>. Accessed on March 14, 2023.

⁶⁰ Food & Drug Administration. Class I and Class II Device Exemptions. Available at: <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions>. Accessed on May 30, 2023.

devices that lack FDA marketing authorization (87 FR 38511). In the absence of evidence that the renal dialysis equipment or supply is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization, the equipment or supply would not meet the TPNIES newness criterion under § 413.236(b)(2).

We received one application for the TPNIES for CY 2024. A discussion of the application is presented below.

3. CY 2024 TPNIES Application for Buzzy® Pro

Pain Care Labs™ submitted an application for the TPNIES for Buzzy® Pro for CY 2024. Buzzy® Pro is one of several models of the Buzzy® device. The Buzzy® device is intended to control pain associated with needle procedures and for temporary relief of minor injuries. Buzzy® Pro is a palm-sized external use vibration device used with unique ice packs and is intended to temporarily desensitize and physiologically block pain associated with dialysis cannulation. The applicant stated that dialysis cannulation pain affects 12 to 80 percent of dialysis patients and is a substantial contributor to reduced quality of life.^{61 62} The applicant further stated that cannulation pain is associated with fear of the cannulation process, the decision to undergo hemodialysis and sometimes the hemodialysis itself.

The applicant described the steps for using Buzzy® Pro during dialysis: (1) thread the hands free strap or regular tourniquet through the ice pack and the device so that the ice pack is on the concave side of the device; (2) attach the device and the ice directly over the site; (3) activate the vibration toggle switch and leave in place 30 to 120 seconds; (4) during cannulation, move the device proximally so the dot on the side opposite the switch is 2 to 3 cm proximal to the cannulation site; (5) clean the site per cannulation protocol; and (6) remove the device after the painful part of procedure is completed.

a. Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item

⁶¹ Kosmadakis G, Amara I, Costel G. Pain on arteriovenous fistula cannulation: A narrative review. *Semin Dial* 2021;34(4):275–84 doi: 10.1111/sdi.12979 [published Online First: 20210507].

⁶² Kosmadakis G, Amara B, Costel G, Lescure C. Pain associated with arteriovenous fistula cannulation: Still a problem. *Nephrol Ther* 2022;18(1):59–62 doi: 10.1016/j.nephro.2021.05.002 [published Online First: 20210618].

has been designated by CMS as a renal dialysis service under § 413.171, pain management associated with dialysis cannulation is a service that is furnished to individuals for the treatment of ESRD and is essential for the delivery of maintenance dialysis, and therefore would be considered a renal dialysis service under § 413.171.

b. Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that it is seeking 510(k) marketing authorization from the FDA for a new utility and design of Buzzy® created for dialysis fistulae sites, patented in 2022 under the name Buzzy® Pro. To be eligible for the TPNIES, the applicant must apply within 3 years of the FDA marketing authorization date and receive FDA marketing authorization by the HCPCS Level II deadline of July 3, 2023.

The applicant submitted the indications for use portion of its FDA 510(k) application that identifies Buzzy® as all Buzzy® models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal and Pro to control pain associated with needle procedures including dialysis and the temporary relief of minor injuries. The applicant provided supplemental information in a document titled “510(k) Summary” that included a comparison table of the Predicate Device (K130631) to the Subject Device (K202993). The document indicated that only the Buzzy® Pro model is recommended for dialysis. The document also indicated that Buzzy® Pro is identical to the predicate device in terms of materials, vibration motor, circuitry, functionality, and intended use; differs only in shape but is comparable in size to the predicate device; and Buzzy® Pro is distinguished by its rectangular shape to offer users a more professional looking alternative to the bee-shape of the other device. We would be interested in better understanding the way in which the Buzzy® Pro, that is the subject of this TPNIES application, differs from the other Buzzy® models and whether Buzzy® Pro is indicated for adult versus pediatric patients, or both. We note that to satisfy the newness criterion, the FDA 510(k) marketing authorization must have been issued within 3 years covering the specific device and model that is the subject of the TPNIES application. We welcome public comment on this issue.

c. Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that it expects Buzzy® Pro would be commercially available immediately after receiving FDA marketing authorization.

d. HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II application by the HCPCS Level II application deadline of July 3, 2023, the applicant stated that it intends to apply by the deadline.

e. Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(1) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant presented two substantial clinical improvement claims. First, the applicant stated that Buzzy® Pro controls needle pain for dialysis. Specifically, per the applicant, Buzzy® Pro makes cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Second, the applicant stated that Buzzy® Pro reduces needle fear.

With respect to the claim that Buzzy® Pro controls needle pain for dialysis, the applicant stated that currently, the most effective options for dialysis cannulation pain are the topical anesthetic, EMLA® and vapocoolant spray.⁶³ Per the applicant, systematic reviews recommend against vapocoolant use due to lack of efficacy⁶⁴ and EMLA® incurs \$15 cost per use and

takes 1 hour to become effective. The applicant asserted that the Buzzy® device has been shown to be superior to vapocoolant spray⁶⁵ and equivalent to topical anesthetics EMLA® and LMX® at a fraction of the cost and time.^{66, 67} The applicant stated that while ice is effective for reducing dialysis pain for both adults and children, it is messy and inferior. The applicant further stated that a Buzzy® device cannulation study in adults found that ice is only 10 percent of the effect, with the mechanical gate control neuromodulation (vibration) providing 90 percent of the pain relief.⁶⁸

With respect to the claim that Buzzy® Pro reduces needle fear, the applicant stated that 25 to 47 percent of chronic kidney patients have needle fear.⁶⁹ The applicant further stated that the Centers for Disease Control and Prevention (CDC) recommends vibrating cold devices for needle fear in children, and cold devices with a buzzer for adults.⁷⁰ The applicant also stated that meta-analyses demonstrate significant fear reduction with Buzzy® device,⁷¹ and a New Zealand study demonstrated improved adherence to Bicillin injections with fear reduced 50 percent after three uses of Buzzy® device.⁷² The

⁶⁵ Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device. *Clin J Pain* 2009;25(8):705–10 doi: 10.1097/AJP.0b013e3181af1236 [published Online First: 2009/11/19].

⁶⁶ Lescop K, Joret I, Delbos P, et al. The effectiveness of the Buzzy® device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomised, non-inferiority study. *Int J Nurs Stud* 2021;113:103803 doi: 10.1016/j.ijnurstu.2020.103803 [published Online First: 20201019].

⁶⁷ Potts DA, Davis KF, Elci OU, Fein JA. A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial. *Pediatr Emerg Care* 2017 doi: 10.1097/pec.0000000000001041 [published Online First: 2017/01/26].

⁶⁸ Abidin NH. Assessing The Effectiveness Of A Thermomechanical Device (Buzzy®) In Reducing Venous Cannulation Pain In Adult Patients. *Middle East Journal of Anesthesiology* 2018;25(1):61–67.

⁶⁹ Duncanson E, Le Leu RK, Shanahan L, et al. The prevalence and evidence-based management of needle fear in adults with chronic disease: A scoping review. *PLoS One* 2021;16(6):e0253048 doi: 10.1371/journal.pone.0253048 [published Online First: 20210610].

⁷⁰ Easy to Read: Needle Phobia. Available at: <https://www.cdc.gov/ncbddd/humandevlopment/covid-19/needle-phobia/index.html> Accessed March 9, 2023.

⁷¹ Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the Buzzy® Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis. *Clin J Pain* 2019 doi: 10.1097/ajp.0000000000000690 [published Online First: 2019/03/05].

⁷² Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin

⁶³ Çelik G, Özbek O, Yılmaz M, Duman I, Özbek S, Apiliogullari S. Vapocoolant spray vs lidocaine/prilocaine cream for reducing the pain of venipuncture in hemodialysis patients: a randomized, placebo-controlled, crossover study. *Int J Med Sci* 2011;8(7):623–7 doi: 10.7150/ijms.8.623 [published Online First: 20111012].

⁶⁴ Hogan ME, Smart S, Shah V, Taddio A. A systematic review of vapocoolants for reducing pain from venipuncture and venous cannulation in children and adults. *J Emerg Med* 2014;47(6):736–49 doi: 10.1016/j.jemermed.2014.06.028 [published Online First: 20140829].

applicant also stated that Buzzy® device is indicated by Health Canada to “control pain and fear from needles” and is used for fearful dialysis patients in the Netherlands.

The applicant submitted 33 unique sources of evidence with its application in support of its claims of substantial clinical improvement. Thirty of the sources that were submitted examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. One article examined the effect of cryotherapy on pediatric pain management at the arteriovenous fistula site during hemodialysis.⁷³ Because the study did not examine the effect of external cold and vibration devices such as the Buzzy® device or more specifically the device that is the subject of this TPNIES application, Buzzy® Pro, in managing dialysis related pain or

injections in the rheumatic fever population of Counties Manukau District Health Board. *J Paediatr Child Health* 2014;50(2):112–7 doi: 10.1111/jpc.12400 [published Online First: 2013/10/19].

⁷³ Attia, A., Hassan, A. Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis. *International Journal of Nursing Sciences* 2017; (4) 46–51.

fear, it was not directly applicable to the applicant’s substantial clinical improvement claims. One article evaluated the effectiveness of distraction cards, in pediatrics in reducing pain and anxiety during intramuscular injection.⁷⁴ Because the study did not examine the effect of external cold and vibration devices such as the Buzzy® device or the Buzzy® Pro device in managing dialysis-related pain or fear, it was not directly applicable to the applicant’s substantial clinical improvement claims. One document labeled as Dutch guidelines was submitted in non-English text and thus, was not readily accessible to our review team.

The applicant also submitted a list of references, referred to as a literature review, that pertained to the applicant’s products, among which, the Buzzy® device was listed as relieving or reducing needle pain and fear and for needle procedures and for musculoskeletal pain.

In a document titled “Summary of Clinical Evidence—relief of needle pain

⁷⁴ Sahiner, N., Turkmen, A. The Effect of Distraction Cards on Reducing Pain and Anxiety During Intramuscular Injection in Children. *Worldviews on Evidence-Based Nursing* 2019; 1–6.

and fear,” the applicant presented the study objectives and key features of 29⁷⁵ of the 30 submitted sources that examined the effect of external cold and vibration devices, including the Buzzy® device, though not Buzzy® Pro, during needle procedures other than dialysis cannulation. The document identified several additional sources that were not submitted by the applicant. Finally, the applicant submitted a document titled “Buzzy Fear reduction rationale and table” that duplicated information already captured in the “Summary of Clinical Evidence—relief of needle pain and fear” document. Table 10 below lists the 29 sources that were both identified by the applicant in the “Summary of Clinical Evidence—relief of needle pain and fear” document and that were submitted. We have not included sources that were mentioned by the applicant, but not submitted to us.

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⁷⁵ The following source was not included in the summary table: Redfern RE, Chen JT, Sibrel S, Effects of Thermomechanical Stimulation during Vaccination on Anxiety, Pain, and Satisfaction in Pediatric Patients: A Randomized Controlled Trial. *J Pediatr Nurs*.2018.38: 1–7.

TABLE 10: Applicant's Substantial Clinical Improvement Sources

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
(1) O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1138 P: 3 – 18 y/o (2) O: Anxiety reduction F: Systematic Review and Meta-analysis N=1138 P: 2-17y	Buzzy	(1) Self-Reported pain reduction - 1.11; 95% [CI]: -1.52 to -0.70; P<0.0001) Of 4 studies only assessing lab draws, IV catheter/venipuncture procedures (SMD: -1.30; 95% CI: -1.84 to -0.76 P<0.00001) (2) (Pain reduction -1.11; 95% confidence interval [CI]: -1.52 to -0.70; P<0.0001), anxiety reduction (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001)	Ballard A Khadra C, Adler S, Doyon- Trottier E, Le May S. <i>Efficacy of the Buzzy Device for Pain Management during Needle-Related Procedures: A Systematic Review and Meta-analysis.</i> Clin J Pain. 2019 June; 35(6):532-543.
O: Pain relief and anxiety reduction for pediatric needle procedures F: Systematic review and meta-analysis N=1479 P: 2 – 18 y/o	Multiple devices	Meta-regression demonstrated a significant negative correlation of pain score with age. For children at 8.5 years, cold vibration reduced the pain score by 0.13 averagely for every increment in year compared with controls (MD -0.13; 95% CI: -0.25, -0.01)	Su HC, Hsieh CW, Lai NM, Chou PY, Lin PH, Chen KH. <i>Using vibrating and cold device for pain relievers in children: a systematic review and meta-analysis of randomized controlled trials.</i> J Pediatr Nurs. 2021 Mar 15; 61:23-33.
O: Pain relief for cannulation in pediatrics F: RCT: Buzzy compared to LMX topical anesthetic N=173 P: 18 months – 17 y/o	Buzzy M-stim only	There were no statistically significant differences among treatment groups based on the observational measures of pain or the self-report measures of pain. Findings support the use of both mechanical vibration and topical anesthetic as effective in children regardless of age group or sex.	Bahorski JS, Hauber RP, Hanks C, Johnson M, Mundy K, Ranner D, Stoutamire B, Gordon G. <i>Mitigating procedural pain during venipuncture in a pediatric population: A randomized factorial study.</i> Int J Nurs Stud. 2015 Oct;52(10):1553-64.
O: Pain relief and first stick vascular access success in pediatric emergency F: RCT: Buzzy v. Vapocoolant N=81 P: 4 – 18 y/o	Buzzy	Vascular access success more likely w/ Buzzy: (odds ratio, 3.05; 95% CI, 1.03- 9.02), p=.040); Self-reported pain scores lower with Buzzy: (-2; 95% CI, -4 to 0) than with vapocoolant (p=.029). Parent reported pain scores lower with Buzzy (-2; 95% CI -4 to -2) than vapocoolant (p=.005).	Baxter AL, Cohen LL, McElvery HL, Lawson ML, von Bacyr CL. <i>An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department.</i> Pediatr Emerg Care. 2011 Dec;27(12):1151-6.
(1) O: Pain relief in adult vascular access F: RCT: Buzzy v. Vapocoolant N=31 P: 18+ Years Hospital employees (2) O: Pain relief with cannulation on the dorsum of hand F: Crossover trial rated with VAS N=31 P: Adult healthcare workers	Buzzy	(1) In a crossover trial, Buzzy reduced angiocath placement pain (mean 9.9 mm, 95% [CI] 0.82-19, P=0.035, SD 16) compared to vapocoolant (mean 7.9 mm, 95% [CI]-1.8-17.7, P=0.1, SD 16.9) (2) Each 20mm of pre-procedural fear increased the likelihood of a successful intervention pain relief (odds ratio 2, P=0.043).	Baxter AL, Leong T, Mathew B. <i>External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device.</i> Clin J Pain. 2009 Oct;25(8):705-10.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
(1) O: Pain and anxiety relief in vascular access procedures in children F: RCT: Buzzy, Buzzy + Cartoons, Cartoons alone, Control/nothing. N=150 P: Mean age 9.4 years (2) O: Fear reduction using Buzzy v. Cartoons v. Nothing v. Buzzy + Cartoons F: RCT N=150 P: Pediatric 5-12 years	Buzzy	(1) Pain: "Buzzy was highly effective in children younger than 9 (p=0.04). Also, a significant efficacy was recorded in the Buzzy and Cartoon group (p=0.04) for the nurse's perception of the child's pain, and in the Buzzy group for the mother's perception of the child's pain (p=0.002)." Anxiety: "Particularly, the difference was statistically significant in the Buzzy (p=0.03) and the Buzzy and animated Cartoon groups (p=0.02) for nurses' perception of the child's anxiety, and in the Buzzy group for mothers' perception of anxiety (p=0.03)." (2) (Children's Emotional Manifestation Scale for anxiety: per nursing and mother evaluation) Nothing -0.26 v. Buzzy -0.86 P=.03. Nothing -0.26 v. Buzzy + Cartoons -0.89 P=.02 Nothing -0.26 v. Cartoons alone -0.73 P=.09).	Bergomi P, Scudeller L, Pintaldi S, Dal Molin A. <i>Efficacy of Non-pharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audio-visual distraction and External Cold and Vibration</i> . J Pediatr Nurs. 2018 Sep-Oct; 42: e66-e72.
O: Pain reduction comparison in children during vascular access F: RCT: Buzzy, Bubbles, and Control N=96 P: 3 – 6 y/o	Buzzy	Pain scores were lower in the groups of Buzzy and blowing soap bubbles than the control group. There was no statistical difference between Self Report, Parent Report, Nurse Report, or Researcher Report between Buzzy and Bubbles. The differences between Buzzy or Bubbles and Control was significant for all P=.0000.	Binay Ş, Bilsin E, Gerçeker GÖ, Kahraman A, Bal-Yılmaz H. <i>Comparison of the Effectiveness of Two Different Methods of Decreasing Pain During Phlebotomy in Children: A Randomized Controlled Trial</i> . J Perianesth Nurs. 2019 Feb 20 S1089-9472(18)30414-3.
O: Superiority trial of pain relief during vascular access F: RCT: Buzzy, Handheld computer distraction N=200 P: 4-12 y/o	Buzzy	No significant difference between a handheld computer distraction and Buzzy, median (IQR) = 3.0 (1.0–4.8) and 2.0 (1.0–4.8), respectively, P = 0.72.	Cozzi G, Crevatin F, Dri V, Bertossa G, Rizzitelli P, Matassi D, Minute M, Ronfani L, Barbi E. <i>Distraction Using Buzzy or Handheld Computers During Venipuncture</i> . Pediatr Emerg Care. 2018 Dec 27.
O: Pain relief during pediatric vascular access F: RCT: Virtual Reality (VR) versus Buzzy N=121 P: 7 - 12 y/o	Buzzy	Buzzy resulted in lower pain than VR and significantly better than control, P = 0.000. Buzzy n=40; 1.5 +/- .2SD versus VR n=41; 2 +/- .2SD, p<.0001).	Gerçeker GÖ, Binay Ş, Bilsin E, Kahraman A, Yılmaz HB. <i>Effects of Virtual Reality and External Cold and Vibration on Pain in 7- to 12-year- old Children During Phlebotomy: A Randomized Controlled trial</i> . J Perianesth Nurs. 2018 Mar 17.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Pain Relief for vascular access with Buzzy, Buzzy + Distraction, Distraction, and Control F: RCT: 4 arm trial N=218 P: 6 - 12 y/o	Buzzy	All groups using Buzzy had significantly reduced pain ($P < 0.001$) compared to the control group. Lowest pain measured w/Buzzy in combination w/DistrAction Cards.	Inal S., Kelleci M. <i>The Effect of External Thermomechanical Stimulation and Distraction on Reducing Pain Experienced by Children During Blood Drawing</i> . <i>Pediatr Emerg Care</i> . 2020 Feb;36(2):66-69.
(1) O: Pain relief during vascular access in pediatric patients F: RCT: [Buzzy v. control] N=120 P: 6 - 12 y/o (2) O: Pain and anxiety relief with lab draws F: RCT using Child Pain Scale N=120 P: 6-12y/o	Buzzy	(1) Lower pain ($p < .001$) and anxiety ($p < .001$ w/ Buzzy) compared to the control group. (2) (Lower pain ($p < .001$) and anxiety with Buzzy. CAPS Parent reported 1.61(Buzzy) v. 3.36 (Control) ($p < .001$))	Inal S, Kelleci M. <i>Relief of pain during blood specimen collection in pediatric patients</i> . <i>MCN Am J Matern Child Nurs</i> . 2012 Sep;37(5):339-45. PMID: 22895207.
(1) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o (2) O: Pain, stress cortisol level, and fear relief during vascular access comparing Buzzy, Jet Lidocaine, Bubbles and aromatherapy F: RCT N=195, 39 x 5 groups P: 5 – 10 y/o	Buzzy	“A significant difference was found between the intervention and control groups in terms of levels of pain during and after phlebotomy in favor of the Buzzy group ($p < 0.05$).” (2) (“children in the Buzzy group were less frightened during phlebotomy (CFS 1.33 v. 2.66 $p < 0.05$).” “There was a significant difference between intervention and control groups fear levels in favor of the Buzzy group during phlebotomy ($p < 0.05$).”	Küçük Alemdar D, Yaman Aktaş Y. <i>The use of the Buzzy, Jet lidocaine, bubble-blowing and aromatherapy for reducing pediatric pain, stress and fear associated with phlebotomy</i> . <i>J Pediatr Nurs</i> . 2019 Jan 30 S0882-5963(18)30352- X.
O: Pain and anxiety in adults during cannulation using Buzzy or control. F: RCT N=100 P: Mean age: 49.6 +/- 13.8y	Buzzy	Pain was less than expected in 44/50 Buzzy patients and 0/50 control, and more than expected in no Buzzy patients and 6/50 control ($P < .000$), with overall less pain (1.04 v 5.32) and greater satisfaction. (95.3 v 2.12) $P < .001$. There was no difference in pulse, state, or trait anxiety before or after cannulation.	Pakiş Çetin S, Çevik K. <i>Effects of Vibration and Cold Application on Pain and Anxiety During Intravenous Catheterization</i> . <i>J Perianesth Nurs</i> . 2019 Aug;34(4):701-709.
O: Pain relief during vascular access in children with cognitive impairment F: RCT: Buzzy v. Control N=70 P: Median age – 9 y/o	Buzzy	“Reported no or mild procedural pain in 32 cases (91.4%) in the Buzzy group and in 22 cases (61.1%) in the no-intervention group ($p = 0.003$).”	Schreiber S, Cozzi G, Rutigliano R, Assandro P, Tubaro M, Cortellazzo Wiel L, Ronfani L, Barbi E. <i>Analgesia by cooling vibration during venipuncture in children with cognitive difficulties</i> . <i>Acta Paediatr</i> . 2016 Jan;105(1): e12-6.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Efficacy of Buzzy for pain reduction in children F: RCT N=72 P: 3 – 10 y/o	Buzzy	Buzzy pain 3.65 vs Magic Glove 4.67 (p=.039).	Susam V. Friedel M, Basile P, Ferri P, Bonetti L. <i>Efficacy of the Buzzy System for pain relief during venipuncture in children: a randomized controlled trial.</i> Acta Biomed. 2018 Jul 18;89(6-S):6-16.
(1) O: Effect of Buzzy, distraction cards, and balloons in reducing pain and anxiety in children receiving procedure requiring vascular access F: RCT N=180 P: 7 – 12 y/o (2) O: Fear reduction with venipuncture F: RCT with CFS N=180 P: pediatrics 9.3 +/- 1.9 years	Buzzy	(1) Lowest pain scores with Buzzy (1.90±1.34) vs Distracting cards (3.17±2.13) vs Balloon inflating (2.83±1.41) vs control (4.15±1.29), (p=0.012) (2) (Fear with Children's Fear Scale lowest with Buzzy (0.61) versus control (3.17), one way ANOVA with 4 arms p=.13 "clinically significant rather than statistically significant." – p <.0001 if Buzzy compared to control, p=.003 if compared to Balloon inflating (CFS 1.19).	Tork HM <i>Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department.</i> Am J Nursing Science 2017 Feb;6(2):26- 32.
O: Effect of vibration on outpatient vascular access in children F: Retrospective review N=64 P: 4 – 18 y/o	Buzzy	"21 of the 26 [phlebotomists'] (80.8%) responses provided indicated that the device made the procedure easier; the other 5 claimed that it had no effect."	Whelan HM, Kunselman AR, Thomas NJ, Moore J, Tamburro RF. <i>The impact of a locally applied vibrating device on outpatient venipuncture in children.</i> Clin Pediatr (Phila). 2014Oct;53(12):1189-95.
(1) O: Effect of vibration in reducing needle pain in children F: Systematic review N= 264 P: 0 - 18 y/o (2) O: Identify, evaluate and synthesize evidence of the effectiveness of vibratory stimulation to reduce needle-related procedural pain in children aged 18 years and younger. F: Systematic Review N=n/a P: 0 – 18 y/o	Buzzy	(1) "The effect size for the Buzzy tended to be higher than that for the other devices." "Buzzy self-rated pain (n=): -0.94, [95% CI]: -1.54, -0.35) p<.00001. [With Buzzy] the effect on the child's anxiety (SMD: -1.03, 95% CI: -1.85 to -0.20 p<.00001) was significant." (2) Comparison devices DentalVibe and Vibrational Anesthesia Device used primarily or exclusively for Dental procedures. "The effect size for the Buzzy tended to be higher than that for the other devices. Overall, vibratory stimulation was significantly effective: self-rated pain: -0.55, 95% confidence interval [95% CI]: -0.92 to -0.18) observer-rated pain outcomes (SMD: -0.47, 95% CI: -0.76 to -0.18)."	Ueki S, Yamagami Y, Makimoto K. <i>Effectiveness of vibratory stimulation on needle-related procedural pain in children: a systematic review.</i> JBI Database System Rev Implement Rep. 2019 Jul;17(7):1428-1463.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors F: Abstract N=90 P: Adult men	Buzzy	“Results indicate that the use of the Buzzy device was an effective method of reducing the pain of phlebotomy and increasing phlebotomy satisfaction in healthy adult male blood donors.” [N=90, Pain 20.93 +/- 15.1 versus 35.23 +/- 19.3, p=.004, satisfaction Buzzy 76.0 +/- 23.7 v. 55.26 +/- 34.8 control, (p=.031)].	Yilmaz D., Heper Y., Gözler. <i>Effect of the Use of Buzzy during Phlebotomy on Pain and Individual Satisfaction in Blood Donors. Pain Management Nursing</i> . 2017 Aug;18(4):260-267. PMID: 28601479.
(1) O: Pain relief during intraoral injections using FLACC F: RCT N=50 P: 5-10 y/o (2) O: Oral dental injections F: RCT FLACC N=50 P: 5-10 years	Buzzy	(1) Conclusion: “Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures”. 1.4 Buzzy, 3.96 Conventional using FLACC, p<.05 (2) “Buzzy® can reduce pain and anxiety during local anesthetic delivery for various dental procedures.” FLACC 1.4 Buzzy, 3.96 Conventional, p<.05	Suohu T, Sharma S, Marwah N, et al. A Comparative Evaluation of Pain Perception and Comfort of a Patient Using Conventional Syringe and Buzzy System. <i>Int J Clin Pediatr Dent</i> 2020;13(1):27-30.
O: Pain and anxiety relief for cannulation F: RCT VAS anxiety VAS pain N=176 P: 7-12 y/o	Buzzy	(WBFS pain Buzzy 2.75, Control 5.7 p=0.000, VAS pain Buzzy 1.66, Control 4.09 p=.000; VAS anxiety Buzzy 0.94, Control 2.09 p=.000; VAS observer anxiety Buzzy 0.92, Control 2.14 p=.000.).	Canbulat N, Ayhan F, Inal S. <i>Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients. Pain Manag Nurs</i> . 2015 Feb;16(1):33-9.
O: Pain and anxiety relief for vascular access with Child Fear Score F: RCT Virtual Reality v. Distraction cards v. Buzzy v control N=142 P: 7-12 y/o	Buzzy	“According to all raters, the Buzzy® group had the lowest mean CFS score, followed by the VR, DC, and control groups (p < 0.05).”	Erdogan B, Ozdemir AA. <i>The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction Cards, Virtual Reality and Buzzy (Randomized Controlled Trial)</i> . <i>J Pediatr Nurs</i> . May-Jun 2021;58:e54-e62.
O: Pain, fear and anxiety from vaccination F: Systematic Review 27 articles N=n/a P: 4 – 15 years	Buzzy	“This review found consistent evidence for reduction in pain, distress and/or fear with interventions that combined cooling and vibrating together...” [pooled data not reported].	Lee VY, Caillaud C, Fong J, Edwards KM. <i>Improving vaccine-related pain, distress or fear in healthy children and adolescents-a systematic search of patient-focused interventions. Hum Vaccin Immunother</i> . 2018;14(11):2737-2747.
O: Anxiety and pain reduction with cannulation F: RCT Buzzy v control N=105 P: Elective Surgical Adults	Buzzy	(In subjects who reported higher pre procedure anxiety, the experimental [Buzzy] group reported lower pain (0.84 ± 0.50) than the control group (3.92± 0.58).	Redfern RE, Micham J, Sievert D, Chen JT. <i>Effects of Thermomechanical Stimulation During Intravenous Catheter Insertion in Adults: A Prospective Randomized Study. J Infus Nurs</i> . 2018 Sept/Oct;41(5):294-300.

O: Study objective; F: Study format; N: Number of participants; P: Study population			
Study Description	Test Article	Results	Reference Title
O: Pain relief with flu vaccination F: RCT VAS, 10-point satisfaction scale N=497 P: Adult employees influenza vaccine clinic	Buzzy	(pain 0.87 v 1.12 p=.035, better than previous experiences 62% Buzzy 23.9% control p<.0001.) “Buzzy can be used in adult patients to reduce pain during immunization and is especially effective in those with high levels of anxiety.”	Redfern RE, Micham J, Seegert S, Chen JT. Influencing Vaccinations: A Buzzy Approach to Ease the Discomfort of a Needle Stick – a prospective, Randomized Controlled Trial. Pain Management Nursing, 2019 Apr;20(2):164-169.
O: Reduction in fear and pain with Bicillin injections F: Observational prospective interventional trial N=118 P: Teens and Adults	Buzzy	(Nonadherent group offered Buzzy, LA bicillin, or both; overall pain and fear reduced 50%, Special needle phobia clinic able to be disbanded.)	Russell K, Nicholson R, Naidu R. Reducing the pain of intramuscular benzathine penicillin injections in the rheumatic fever population of Counties Manukau District Health Board. J Paediatr Child Health. 2014 Feb;50(2):112-7.
O: To investigate the effect of the Buzzy application on pain and satisfaction during injections. F: RCT N=65 P: Average age 52	Buzzy	(Pain 74% reduced, satisfaction 95 v. 84. P<.001 both favor Buzzy).	Sahin M. Effect of Buzzy® application on pain and injection satisfaction in adult patients receiving intramuscular injections. Pain Management Nurs 2018 Dec;19(6):645.
O: Immunization pain and fear reduction Buzzy v. control with TdAP F: RCT Children Fear Scale N=104 P: 7-year-olds	Buzzy	Buzzy: 0.58 +/- 0.63 v. 1.96 +/- 1.13 p=.001 Finding: The experimental group showed significantly lower pain and anxiety levels than the control group during immunization. Conclusions/implications for practice: The combined stimulation of skin with external cold and vibration can be used to reduce pain and anxiety during pediatric immunization.	Sahiner NC, Inal S, Akbay AS. The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. J Perianesth Nurs. 2015 Jun;30(3):228-35.
O: Buzzy Bubbles Shotblocker or nothing for IM injections F: RCT 4 arm N=160 P: 5-10 years	Buzzy	Results: A significant difference was found between the intervention and control groups in terms of levels of pain and fear during IM injection. Pain and fear were notably less in the group of children receiving the Buzzy intervention. Discussion: The Buzzy intervention should be used when children are undergoing IM injections to reduce their levels of pain and fear.	Yilmaz G, Almdar DK. Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear Caused by Intramuscular Injection: A Randomized Controlled Trial. J Emerg Nurs. 2019 Sep;45(5):502-511.

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As stated previously, the applicant must demonstrate that the equipment or supply meets at least one of the following three substantial clinical improvement criteria in order to be eligible for the TPNIES: (1) the item

offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment; (2) the item offers the ability to diagnose a medical condition in the patient population where that medical condition is currently undetectable or

offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods; or (3) the item significantly improves clinical outcomes relative to services or technologies previously available. The applicant stated that

Buzzy® Pro makes dialysis cannulation pain relief available to dialysis patients, which significantly improves clinical outcomes related to depression and discontinuation of dialysis due to needle pain. Therefore, we believe that the applicant is targeting the clinical outcomes criterion (number (3) above). The applicant also stated that Buzzy® Pro reduces needle fear. We did not identify evidence within the application or the submitted materials documenting improved clinical outcomes related to depression or dialysis adherence but would be interested in reviewing such evidence.

With respect to the submitted evidence, it does not appear that the studies reflect the use of (1) Buzzy® Pro, the device that is the subject of the TPNIES application, nor (2) Buzzy® Pro in the context of dialysis cannulation. Specifically, the applicant submitted an application for Buzzy® Pro, indicating that Buzzy® Pro is a new design created for dialysis fistulae sites, patented in 2022. However, the sources submitted were dated prior to the 2022 new design patent date for dialysis fistulae sites. As such, it appears that the sources submitted reflect the use of a predecessor Buzzy® device. In addition, while the applicant's "Summary of Clinical Evidence" document presented sources as evaluating Buzzy® Pro's efficacy in managing vascular access pain or fear, we note that none of these sources appear to evaluate vascular access in the context of dialysis cannulation. The studies evaluated pain and fear in the context of other types of needle procedures, including vaccine or medication injections, blood specimen collection, and intravenous catheter insertion.

It is unclear whether findings of pain or fear reduction from the use of the Buzzy® device in non-dialysis needle procedures could be extrapolated to dialysis cannulation pain or fear. There are several unique features to dialysis cannulation that may limit generalizability. These include the need for regular punctures several times per week, the maintenance of cannulation for several hours during dialysis treatments, the use of substantially larger needle sizes in dialysis, and complications that are associated with frequent vascular access cannulation, such as infections and thrombosis. As such, we question whether outcomes could reasonably be extrapolated as

applicable to patients undergoing dialysis cannulation.

As identified in the table, the majority of the studies provided in support of the applicant's claims reflect pediatric patient experiences. We note that pediatric patients comprise a small proportion, just 0.14 percent, of the total Medicare ESRD patient population (87 FR 67222). As such, the data that is heavily weighted towards the pediatric population may have limited generalizability to the non-pediatric majority of the ESRD patient population.

While the applicant stated that the Buzzy® devices are less expensive than topical anesthetic, we note that cost is not an eligibility criterion for the TPNIES.

It is also unclear whether a single Buzzy® Pro device and its components (for example, tourniquet and ice pack) are intended for single versus multiple patient use in the ESRD facility setting. To the extent that the device or its components are intended for use among multiple patients, we would be interested in data that examines the risk of infection associated with the use of Buzzy® Pro in the dialysis patient population. Additionally, we are not aware of any data that examines the risk of harm to the dialysis access site or any other adverse events associated with use of the Buzzy® Pro in the dialysis patient population, including access and bloodstream infections and thromboses but would be interested in the results of such data.

In addition, the applicant stated that currently, the most effective options for dialysis cannulation pain are topical anesthetics and vapocoolant spray. We would be interested in studies comparing the use of Buzzy® Pro to topical anesthetics or vapocoolant and that demonstrate that Buzzy® Pro significantly improves clinical outcomes of dialysis patients relative to existing available treatments.

We are inviting public comments on whether the Buzzy® Pro meets the substantial clinical improvement criteria for the TPNIES.

f. Capital-Related Assets Criterion (§ 413.236(b)(6))

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, we note that Buzzy®

Pro does not meet the definition of a capital-related asset under § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership that is subject to depreciation.⁷⁶

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2024

In this section of the proposed rule, we identify any items previously approved for the TPNIES and for which payment is continuing for CY 2024. As described in the CY 2023 ESRD PPS final rule, payment for the one item approved for TPNIES, the Tablo® Hemodialysis System, as described by HCPCS code E1629, expires on December, 31, 2023 (87 FR 67216). As such there are no items previously approved for TPNIES for which payment is continuing in CY 2024.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2024

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In December 2021, CMS approved Korsuva™ (difelikefalin) for the TDAPA under the ESRD PPS, effective April 1, 2022. Implementation instructions are specified in CMS Transmittal 11295,⁷⁷ dated March 15, 2022, and available at: <https://www.cms.gov/files/document/r11295CP.pdf>. In this section of the proposed rule, we provide a table that identifies the one new renal dialysis drug that was approved for the TDAPA effective in CY 2022, and for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2024. Table 11 also identifies the product's HCPCS coding information as well as the payment adjustment effective date and end date.

⁷⁶ See also CMS Provider Reimbursement Manual, Chapter 1, section 104.1. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>

⁷⁷ CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022.

TABLE 11: Continuation of Approved Transitional Drug Add-On Payment Adjustments

HCPSC Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0879	Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)	4/1/2022	3/31/2024

III. Calendar Year (CY) 2024 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We

codified this policy in § 413.372 (81 FR 77965).

B. Proposed Annual Payment Rate Update for CY 2024

1. CY 2024 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this proposed rule, the proposed ESRD PPS base rate is \$269.99, which reflects the application of the proposed CY 2024 wage index budget-neutrality adjustment factor of 0.999652 and the proposed CY 2024 ESRDB market basket percentage increase of 2.0 percent reduced by the proposed productivity adjustment of 0.3 percentage point, that is, 1.7 percent. Accordingly, we are proposing a CY 2024 per treatment payment rate of \$269.99 ($(\$265.57 \times 0.999652) \times 1.017 = \$269.99$) for renal dialysis services furnished by ESRD facilities to individuals with AKI. This proposed payment rate is further adjusted by the wage index, as discussed in the next section of this proposed rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b of this proposed rule. The AKI dialysis payment rate is

adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. As stated previously, we are proposing a CY 2024 AKI dialysis payment rate of \$269.99, adjusted by the ESRD facility's wage index.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to previous ESRD QIP rules at: 75 FR 49030; 76 FR 628; 76 FR 70228; 77 FR 67450; 78 FR 72156; 79 FR 66120; 80 FR 68968; 81 FR 77834; 82 FR 50738; 83 FR 56922; 84 FR 60648; 85 FR 71398; 86 FR 61874; and 87 FR 67136.

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Proposals To Update the Regulation Text for the ESRD QIP

1. Proposal To Revise the Definition of "Minimum Total Performance Score (mTPS)" at § 413.178(a)(8)

In the CY 2019 ESRD PPS final rule, we codified a number of key terms used in the ESRD QIP at § 413.178(a) of our regulations (83 FR 56980 through 56982). One of these terms is "minimum total performance score" (mTPS), which we defined at § 413.178(a)(8) "with respect to a payment year"⁷⁸ as "the total performance score that an ESRD facility would receive if, during the

⁷⁸ In the CY 2023 ESRD PPS final rule, we revised § 413.178(a)(8) to exempt PY 2023 (87 FR 67229).

baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.”

We have recently reevaluated this definition and determined that it should be revised to more accurately capture how we calculate the median of national ESRD facility performance on reporting measures. Although we use data prior to the performance period to calculate these medians, the data may not be from the same time period, or “baseline period” (see § 413.178(a)(2)) used to calculate the 50th percentile of national ESRD facility performance on the clinical measures. Instead, our policy has been to calculate the median of national ESRD facility performance on the ESRD QIP reporting measures using the most recently available data prior to the applicable performance period for the payment year. If there were no data available prior to the first performance period of a new reporting measure, as was the case for the Clinical Depression Screening and Follow-Up reporting measure, we would use a proxy median for purposes of including the reporting measure in our calculation of the mTPS. We selected the values for these proxy medians based on the availability of previous measure data, a facility’s familiarity with similar measures or requirements, and considerations regarding a facility’s ability to comply with new reporting measure requirements during the initial performance periods for a new reporting measure.

We are proposing to update the definition of “minimum total performance score” at § 413.178(a)(8) so that it accurately captures these policies. We are also proposing that, with respect to the adoption of future reporting measures, including the reporting measures proposed in this proposed rule, if there are an insufficient quantity of data available prior to the first performance period of a new reporting measure, we will set a proxy median of zero for the reporting measure until we have sufficient data to calculate the median. We believe that this proposal will provide facilities with additional predictability and transparency regarding our calculation of the mTPS for a payment year. Although many facilities score much higher than zero during the initial performance periods of a new reporting measure, we believe that setting the proxy median at zero where we do not have sufficient data available will

account for the possibility that new reporting measures may have different reporting requirements. For example, a new reporting measure may require a facility to report new or additional data in EQRS in order to be eligible for scoring on the reporting measure. Additionally, a new reporting measure may require that a facility reconsider its internal processes to comply with the reporting requirements and be eligible for scoring. We believe that using a median of 0 for new reporting measures would ensure that the mTPS is calculated based on the worst-case scenario, rather than assuming a median higher than what may be observed once data are available. Setting the proxy median at zero until we have sufficient data available to calculate the median would allow the timely inclusion of a new reporting measure in the ESRD QIP measure set, as well as our calculation of the mTPS, while also encouraging facilities to report the new or additional data that may be specified by that reporting measure so that they are able to receive credit for reporting.

We welcome public comment on this proposal.

2. Proposal To Codify the ESRD QIP Measure Adoption, Retention, and Removal Policies

In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the CY 2019 ESRD PPS final rule (83 FR 56983 through 56985), we finalized eight measure removal factors for the ESRD QIP, and we refer readers to that final rule for details. We also finalized a policy to retain a measure for certain specified reasons, such as when a particular measure addresses a gap in quality so significant that removing the measure could result in poor quality or when a measure addresses a statutorily-required topic, even if one or more of the measure removal factors applies. In the CY 2013 ESRD PPS final rule (77 FR 67475), we also finalized that we would generally remove an ESRD QIP measure using notice and comment rulemaking unless we determined that the continued collection of data on the measure raised patient safety concerns. In that case, we stated that we would promptly remove the measure, immediately notify ESRD facilities and the public through the usual communication channels (including listening sessions, memos, email notification, and website postings), and publish the justification

for the removal in the **Federal Register** during the next rulemaking cycle.

We are proposing to revise 42 CFR 413.178(c) to incorporate these measure adoption, retention, and removal policies. Existing § 413.178(c)(1) through (5) would be consolidated and renumbered as § 413.178(c)(1)(i) through (v), and we would add a new § 413.178(c)(1)(vi), which would codify our policy to adopt measures for the ESRD QIP beyond those that address the topics described at § 413.178(c)(1)(i) through (v). We are also proposing to codify at § 413.178(c)(2) our policies regarding the use of endorsed measures. We are proposing to codify at § 413.178(c)(3) our policy regarding the updating of measure specifications. Additionally, we are proposing to codify at § 413.178(c)(4) our policy regarding measure retention. Finally, we are proposing to codify at § 413.178(c)(5) our policies regarding measure removal. We believe these proposals will make it easier for interested parties to find these policies and will further align the ESRD QIP regulations with the regulations we have codified for other quality reporting programs.

We welcome public comment on these proposals.

C. Proposed Updates to Requirements Beginning With the PY 2026 ESRD QIP

1. PY 2026 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). In this proposed rule, we are proposing to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate clinical measure beginning with PY 2026. We are also proposing to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. Table 12 below summarizes the previously finalized and proposed new measures that we would include in the PY 2026 ESRD QIP measure set. The technical specifications for each of these measures that would apply for PY 2026 can be found in the CMS ESRD Measures Manual for the 2023 Performance Period.⁷⁹

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⁷⁹ <https://www.cms.gov/files/document/esrd-measures-manual-v80.pdf>.

TABLE 12: Previously Finalized and Proposed New Measures for the PY 2026 ESRD QIP Measure Set

Consensus-Based Entity⁸⁰ (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure* Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure** Percentage of HCP who receive a complete COVID-19 vaccination course.
N/A	Facility Commitment to Health Equity, a reporting measure*** Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.

*We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

**We are proposing to update the COVID-19 Vaccination Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

*** We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

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2. Proposal To Adopt the Facility Commitment to Health Equity Reporting Measure Beginning With the PY 2026 ESRD QIP

a. Background

Significant and persistent disparities in healthcare outcomes exist in the U.S. For example, belonging to a racial or ethnic minority group, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, being a member of a religious minority, living in a rural area, being a person with a disability or disabilities, or being near or below the poverty level, is often associated with worse health outcomes.^{81 82 83 84 85 86 87 88 89 90}

Numerous studies have shown that among Medicare beneficiaries, individuals who are racial and ethnic minorities often receive lower quality hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.^{91 92 93 94 95 96} Readmission rates in the Hospital Readmissions Reduction Program have shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including congestive heart failure and acute myocardial infarction.^{97 98 99 100 101} Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower

quality healthcare.¹⁰² Evidence of differences in quality of care received by people from racial and ethnic minority groups show worse health outcomes, including a higher incidence of diabetes complications such as retinopathy.¹⁰³ Additionally, inequities in the drivers of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.¹⁰⁴

In the CY 2022 ESRD PPS proposed rule (86 FR 36362 through 36369), we requested information on our Equity Plan for Improving Quality in Medicare (also referred to as the CMS Framework for Health Equity),¹⁰⁵ which outlines our commitment to close health equity gaps through improved data collection, measurement, and analysis of disparities across programs and policies. The request for information asked for public comment regarding the potential stratification of quality measure results by race and ethnicity and the potential creation of a hospital or facility equity score in CMS quality reporting and value-based purchasing programs, including the ESRD QIP. We received many responses to that request for public comment, and we refer readers to the CY 2022 ESRD PPS final rule for summaries of those comments (86 FR 61934 through 61937). We noted in the CY 2022 ESRD PPS final rule the value of these comments in the continuing development of our health equity

⁸⁰ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

⁸¹ Joynt KE, Orav E, Jha AK. 2011. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA*, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

⁸² Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *BMJ*, 346. Available at: <https://doi.org/10.1136/bmj.f521>.

⁸³ Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. *N Engl J Med*, 371(24), 2298–2308. Available at: doi: 10.1056/NEJMsa1405003.

⁸⁴ Polyakova, M, Udalova V, Kocks, G, Genadek K, Finlay K, Finkelstein AN. 2021. Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. *Health Affairs*, 40(2), 307–316. Available at: <https://doi.org/10.1377/hlthaff.2020.02142>.

⁸⁵ Rural Health Research Gateway. 2018. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: <https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf>.

⁸⁶ HHS Office of Minority Health. 2020. Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.

⁸⁷ Heslin KC, Hall JE. 2021. Sexual Orientation Disparities in Risk Factors for Adverse COVID-19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. *MMWR Morb Mortal Wkly Rep*, 70(5), 149. doi: 10.15585/mmwr.mm7005a1.

⁸⁸ Poteat TC, Reisner SL, Miller M, Wirtz AL. 2020. COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. *medRxiv*. doi: 10.1101/2020.07.21.20159327.

⁸⁹ Vu M, Azmat A, Radejko T, Padela AI. 2016. Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health*, 25(6), 586–593. doi: 10.1089/jwh.2015.5517.

⁹⁰ Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. *Health Psychology*, 35(4), 351–355. <https://doi.org/10.1037/hea0000268>.

⁹¹ CMS Office of Minority Health. 2020. Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at:

⁹² CMS Office of Minority Health. Updated August 2018. Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.

⁹³ Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. 2014. Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. *Ann Rheum Dis*, 73(12), 2107–15. Available at: doi:10.1136/annrheumdis-2013-203494.

⁹⁴ Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. 2019. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. *J Am Geriatr Soc*, 67(8), 1672–1679. Available at: <https://doi.org/10.1111/jgs.15960>.

⁹⁵ Joynt KE, Orav E, Jha AK. 2011. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA*, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

⁹⁶ Tsai TC, Orav EJ, Joynt KE. 2014. Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *Ann Surg*, 259(6), 1086–1090. Available at: doi: 10.1097/SLA.0000000000000326.

⁹⁷ Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. 2011. Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. *Am Heart J*, 162(2), 254–261 e253. Available at: <https://doi.org/10.1016/j.ahj.2011.05.009>.

⁹⁸ Centers for Medicare & Medicaid Services. 2014. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: <https://www.hhs.gov/guidance/document/medicare-hospital-quality-chartbook-performance-report-outcome-measures>.

⁹⁹ CMS Office of Minority Health. Updated August 2018. Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.

¹⁰⁰ Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. 2013. Chronic Obstructive Pulmonary Disease Readmissions at Minority-Serving Institutions. *Ann Am Thorac Soc*, 10(6), 680–684. Available at: <https://doi.org/10.1513/AnnalsATS.201307-223OT>.

¹⁰¹ Joynt KE, Orav E, Jha AK. 2011. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA*, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

¹⁰² Nelson AR. 2003. Unequal Treatment: Report of the Institute of Medicine on Racial and Ethnic Disparities in Healthcare. The Annals of thoracic surgery, 76(4), S1377–S1381. doi: 10.1016/s0003-4975(03)01205-0.

¹⁰³ Peek, ME, Odoms-Young, A, Quinn, MT, Gorawara-Bhat, R, Wilson, SC, & Chin, MH. 2010. Race and Shared Decision-Making: Perspectives of African-Americans with diabetes. *Social Science & Medicine*, 71(1), 1–9. Available at: doi:10.1016/j.socscimed.2010.03.014.

¹⁰⁴ Department of Health and Human Services. 2021. Healthy People 2020: Disparities. Available at: www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.

¹⁰⁵ Centers for Medicare and Medicaid Services. 2022. CMS Framework for Health Equity 2022–2032. Available at: <https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf>. Centers for Medicare & Medicaid Services. 2021. Paving the Way to Equity: A Progress Report. Available at: <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>. Accessed on February 20, 2023. See also, Centers for Medicare & Medicaid Services Office of Minority Health. 2021. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid%20Services%20%28CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input. Accessed on February 20, 2023.

quality measurement efforts, and we stated that we would take the comments into account for future development and expansion of our health equity quality measurement efforts.

The Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission have independently concluded that facility leadership plays an important role in promoting a culture of quality and safety.^{106 107 108} AHRQ research shows that facility boards can influence quality and safety in a variety of ways; not only through strategic initiatives, but also through more direct interactions with frontline workers.¹⁰⁹ The Joint Commission found that a leader who is committed to prioritizing and making patient safety visible through every day actions is a critical part of creating a true culture of safety, which in turn fosters an organizational culture in which patients are treated with dignity and respect.¹¹⁰ Because CMS is also working toward the goal of all patients receiving high-quality healthcare, regardless of individual characteristics, we are also committed to supporting healthcare organizations in building a culture of safety and equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. This includes patients receiving the right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

We believe that strong and committed leadership from dialysis facility executives and board members is essential and can play a role in shifting

organizational culture and advancing equity goals for dialysis facilities. Studies demonstrate that hospital leadership can positively influence culture for better quality, patient outcomes, and experience of care.^{111 112 113} A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in a high-performing hospital with better patient outcomes.¹¹⁴ We believe this conclusion also applies to dialysis facilities, and that the commitment of dialysis facility leadership to health equity would result in a reduction of health disparities in the ESRD population.

Our belief that a leadership commitment to health equity can lead to a reduction of health disparities is also supported by research conducted by the Institute for Healthcare Improvement (IHI), which studied 23 health systems throughout the U.S. and Canada. The IHI's research showed that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among populations that have been disadvantaged by the healthcare system.¹¹⁵ This IHI study specifically identified concrete actions to make advancing health equity a core strategy, including establishing this goal as a leader-driven priority alongside organizational development structures and processes.¹¹⁶ Based upon these findings, we believe that dialysis facility leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals

to assess progress towards achieving equity goals and ensuring high-quality care at dialysis facilities is accessible to all. Based on this well-developed body of evidence, we are proposing to adopt an attestation-based structural reporting measure, Facility Commitment to Health Equity, for the ESRD QIP beginning with PY 2026.

The first pillar of our strategic priorities¹¹⁷ reflects our deep commitment to improvements in health equity by addressing the health disparities that underly our health system. In line with this strategic pillar, we developed this structural measure to assess facility commitment to health equity across five domains (see Table 13 below) using a suite of organizational competencies aimed at achieving health equity for all patients, including but not limited to patients who belong to racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas, and assessment of dialysis facility leadership commitment to them is foundational.

We are proposing to adopt the measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP. Disparities in health equity are tied to worse patient outcomes in the ESRD community. For example, individuals from racial and ethnic minority groups and with lower incomes are less likely to receive recommended care for CKD risk factors and are also less likely to reduce CKD risk through recommended treatment goals.^{118 119 120 121}

¹⁰⁶ Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: <https://psnet.ahrq.gov/primer/leadership-role-improving-safety>.

¹⁰⁷ Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: <https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf>.

¹⁰⁸ See information on launch of new "Health Care Equity Certification" in July 2023 from Joint Commission on Accreditation of Healthcare Organizations, USA, available at: <https://www.jointcommission.org/our-priorities/health-care-equity/health-care-equity-prepublication/>.

¹⁰⁹ Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019: Available at: <https://psnet.ahrq.gov/primer/leadership-role-improving-safety>.

¹¹⁰ Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: <https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf>.

¹¹¹ Bradley EH, Brewster AL, McNatt Z, et al. (2018) How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. *BMJ Qual Saf.*, 27(3), 218–225. doi:10.1136/bmjqs-2017-006574.

¹¹² Smith SA, Yount N, Sorra J. 2017. Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research*, 17(1), 143. doi:10.1186/s12913-017-2078-6.

¹¹³ Keroack MA, Youngberg BJ, Cereze JL, Krsek C, Prellwitz LW, Trevelyan EW. (2007). Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers. *Acad Med.*, 82(12), 1178–86. doi: 10.1097/ACM.0b013e318159e1ff.

¹¹⁴ Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. *The Milbank quarterly*, 91(4), 738–70. doi:10.1111/1468-0009.12032.

¹¹⁵ Mate KS and Wyatt R. 2017. Health Equity Must Be a Strategic Priority. *NEJM Catalyst*. Available at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556>.

¹¹⁶ Mate KS and Wyatt R. 2017. Health Equity Must Be a Strategic Priority. *NEJM Catalyst*. Available at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556>.

¹¹⁷ Brooks-LaSure, C. 2021. My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms>.

¹¹⁸ United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

¹¹⁹ Benjamin O, Lappin SL. End-Stage Renal Disease. Updated 2021 Sep 16. In: Stat Pearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK499861/>.

¹²⁰ Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. *Seminars in Dialysis* 30(3):213–223. doi:10.1111/sdi.12589.

¹²¹ CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: <https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf>.

Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a nephrologist before starting dialysis.¹²² Individuals from racial and ethnic minority groups with ESRD are more likely to have 30-day hospital readmissions when compared to non-Hispanic White patients.¹²³ We believe that this measure is an appropriate measure of ESRD quality of care because it would improve facilities' awareness of the tie between their structural practices and their patient outcomes by reporting these data, thus informing facility practices such that their patients attain better outcomes. We also believe that the proposed measure would incentivize facilities to collect and utilize their data to identify their own critical equity gaps, implement plans to address said gaps, and ensure that they dedicate resources to addressing those gaps. Facilities could analyze data to understand, for example, whether there are any demographic factors (such as race, national origin, primary language, and ethnicity), or social drivers of health (such as housing status and food security) that may be affecting access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, the

measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the proposed measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a state's civil rights laws.

The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.¹²⁴ We have already adopted this measure for the Hospital Inpatient Quality Reporting (IQR) Program, and we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49201) for a discussion of the measure in that program. Other than replacing the term "hospital" with the term "facility," the proposed measure is identical to the Hospital IQR Program measure. The Facility Commitment to Health Equity measure is aligned with the Meaningful Measures Area of "Equity of Care" and

the Meaningful Measures 2.0 goal to "Leverage Quality Measures to Promote Equity and Close Gaps in Care" because it seeks to assess structural health equity issues that could inform facility practices such that their patients attain better outcomes. This measure also supports the Meaningful Measures 2.0 objective to "[c]ommit to a patient-centered approach in quality measure and value-based incentives programs to ensure that quality and safety measures address healthcare equity" because the measure would incentivize facilities to identify their own healthcare equity gaps from a structural perspective.

b. Overview of Measure

The proposed Facility Commitment to Health Equity reporting measure would assess dialysis facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for all populations, including those that have been disadvantaged, marginalized, and underserved by the healthcare system. As previously noted, this includes, but is not limited to: racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table 13 includes the five attestation domains and the elements within each of those domains to which a facility would report an affirmative attestation for the facility to receive points for that domain.

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¹²² Norton, J.M., Moxey-Mims, M.M., Eggers, P.W., Narva, A.S., Star, R.A., Kimmel, P.L., & Rodgers, G.P. (2016). Social Determinants of Racial Disparities in CKD. *Journal of the American Society of Nephrology*: JASN, 27(9), 2576–2595. <https://doi.org/10.1681/ASN.2016010027>.

¹²³ CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf>.

¹²⁴ Centers for Medicare & Medicaid Services. 2021. Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf>.

TABLE 13: The Facility Commitment to Health Equity Measure’s Five Attestations

Attestation	Elements: Select all that apply
	(Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	(A) Our facility collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data) and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using certified EHR technology.
Domain 3: Data Analysis	

Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.

(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.

Domain 4: Quality Improvement

Health disparities are evidence that high-quality care has not been delivered equitably to all patients.* Engagement in quality improvement activities can improve quality of care for all patients.

(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.

Domain 5: Leadership Engagement

Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.

(A) Our facility senior leadership, including chief executives and the entire facility** board of trustees, annually reviews our strategic plan for achieving health equity.

(B) Our facility senior leadership, including chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* After publication of the “List of Measures Under Consideration for December 1, 2022” (2022 MUC List), we clarified the language in Domain 4: “Health disparities are evidence that high quality care has not been delivered *equitably* to all patients.”

** After publication of the 2022 MUC List, we identified that Domain 5 incorrectly referred to the “hospital board of trustees” instead of the “facility board of trustees,” and therefore updated the language in Domain 5 to be more applicable to the ESRD QIP.

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c. Measure Calculation

The proposed Facility Commitment to Health Equity measure consists of five attestation-based questions, each representing a separate domain of commitment. For a facility to affirmatively attest “yes” to a domain, and receive points for that domain, the facility would need to determine that it engages in all of the activities that are included as elements under the domain. A facility that engages in all of the activities for a domain would report an affirmative attestation by answering “yes” to the attestation-based question for that domain. There is no option for a facility to answer “yes” in response to an attestation-based question for a domain if the facility engages in some, but not all, of the activities included as domain elements, and there is also no option for a facility to answer “no” in response to any attestation-based question for a domain. The measure would be expressed as a fraction, and a facility can score either 0, 2, 4, 6, 8, or 10 for the performance period, depending on the number of domains to which a facility positively attests. We are proposing that the measure

denominator would be “ten,” with each domain being represented as two points out of that total ten points, and that the numerator would be calculated as two points for each “yes” answer the facility reports which are then summed together. We chose to award facilities two points for each affirmative response to an attestation-based question so that the maximum number of points a facility could receive for the measure is ten, which is the same maximum number of points that a facility can receive on other ESRD QIP measures.

For example, for Domain 1 (“Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority”), a facility would evaluate and determine whether its strategic plan satisfies all of the elements described in (A) through (D) (see Table 13). If the facility’s plan satisfies all four of these elements, the facility would respond “yes” to the attestation-based question for Domain 1 and receive two (2) points for that response. If the facility determined that its strategic plan satisfies elements (A) and (B) but not (C) and (D), the facility would not be able to respond “yes” to

Domain 1 and would not receive any points for that domain.

The numerator would be calculated as the sum of the points the facility earns for responding “yes” to the attestation-based questions. For example, a facility that responds “yes” to all five attestation-based questions would receive the maximum 10 points (two points for each of the five “yes” responses). A facility that responds “yes” to three of the attestation-based questions would receive six points.

We are proposing that the Facility Commitment to Health Equity reporting measure would be added to the Reporting Measure Domain, as discussed further in section IV.C.6 of this proposed rule. Technical specifications for the proposed measure can be found in the ESRD QIP CY 2024 Technical Measure Specifications, which are available at: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/esrdqip/061_technicalspecifications. Consistent with case minimums we have adopted for our other ESRD QIP reporting measures, we are proposing that facilities must have 11 qualifying patients and a CCN open

date before September 1 of the performance period that applies to the program year in order to be eligible for scoring on the Facility Commitment to Health Equity reporting measure.

d. Data Submission and Reporting

We are proposing that facilities would be required to submit data needed to calculate the Facility Commitment to Health Equity measure once on an annual basis using EQRS beginning with PY 2026. We are proposing that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures. For example, for the PY 2026 ESRD QIP, facilities would need to report data on the measure by the end of the December data reporting month in CY 2024. As described in Table 17 of this proposed rule, we are proposing performance standards for the Facility Commitment to Health Equity reporting measure. We are proposing a 12-month performance period for the measure. We are also proposing that facilities would be required to follow the submission and reporting requirements for web-based measures for the ESRD QIP posted on the QualityNet website: <https://qualitynet.cms.gov/esrd/esrdqip>.

e. Review by the Measure Applications Partnership

We included the Facility Commitment to Health Equity measure as a measure under consideration for the ESRD QIP on the publicly available “List of Measures Under Consideration for December 1, 2022” (MUC List), a list of measures under consideration for use in various Medicare quality programs.¹²⁵ The CBE-convened Measure Applications Partnership (MAP) Health Equity Advisory Group reviewed the MUC List and the Facility Commitment to Health Equity measure (MUC2022–027) in detail on December 6–7, 2022.¹²⁶ The Health Equity Advisory Group expressed concern that this is more of a “checklist” measure that may not directly address health inequities at a systemic level, but the advisory group generally agreed that a structural measure such as this one represents progress toward improving equitable

care.¹²⁷ In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List, and the MAP Hospital Workgroup reviewed the 2022 MUC List on December 13–14, 2022.¹²⁸ The MAP Hospital Workgroup recognized that reducing health care disparities would represent a substantial benefit to overall quality of care, but expressed reservations about the measure’s link to clinical outcomes; the MAP Hospital Workgroup members voted to conditionally support the measure for rulemaking pending: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results; and (4) verifying attestation provided by the accountable entities.¹²⁹ Thereafter, the MAP Coordinating Committee deliberated on January 24–25, 2023 and ultimately voted to conditionally support the Facility Commitment to Health Equity measure for rulemaking with the same conditions.¹³⁰

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other

CBE-endorsed measures on this topic, and therefore we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

We are proposing to publicly display the facility-specific results for the Facility Commitment to Health Equity reporting measure on an annual basis through our *Care Compare* website at: <https://www.medicare.gov/care-compare/>. We anticipate making the first public report available in January 2026.

We invite public comment on this proposal.

3. Proposed Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With PY 2026

a. Background

On January 31, 2020, the Secretary of the Department of Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named “coronavirus disease 2019” (COVID–19).¹³¹ Subsequently, the measure was adopted across multiple quality reporting programs including the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), the Hospital Inpatient Quality Reporting Program (86 FR 45374), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Outpatient Quality Reporting Program (86 FR 63824 through 63833), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Ambulatory Surgical Center Quality Reporting Program (86 FR 63875 through 63883), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396). COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.1 million deaths in the United States as of March 27, 2023.¹³² In recognition of the ongoing

¹²⁵ Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. Available at: <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>.

¹²⁶ Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹²⁷ Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹²⁸ Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Rural Health Advisory Group, at <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>; see also, MAP Hospital Workgroup, available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹²⁹ Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹³⁰ Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹³¹ U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. 2020. Determination that a Public Health Emergency Exists. Available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

¹³² Centers for Disease Control and Prevention. COVID Data Tracker. Accessed March 27, 2023.

significance and complexity of COVID-19, the Secretary has renewed the PHE on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 9, 2023.¹³³ The PHE expired on May 11, 2023; however, HHS has stated that the public health response to COVID-19 remains a public health priority with a whole of government approach to combatting the virus, including through vaccination efforts.¹³⁴

As we stated in the CY 2023 ESRD PPS final rule (87 FR 67244) and in our Revised Guidance for Staff Vaccination Requirements,¹³⁵ vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID-19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including dialysis facilities, in order to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities throughout the PHE and beyond. Prior to the publication of the CY 2023 ESRD PPS final rule on November 7, 2022, the FDA had approved or issued emergency use authorizations (EUs) for COVID-19 vaccines for adults manufactured by Pfizer-BioNTech,¹³⁶ Moderna,¹³⁷ and

Janssen.¹³⁸ The populations for which all three vaccines were authorized at that time included individuals 18 years of age and older, and the Pfizer-BioNTech vaccine was authorized for ages 12 and older. The FDA issued an approval for the Pfizer-BioNTech vaccine, now marketed as Comirnaty, on August 23, 2021.¹³⁹ Additionally, the FDA issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022¹⁴⁰ and an EUA for the Novavax adjuvanted vaccine on July 13, 2022.¹⁴¹ The FDA also issued EUs for single booster doses of the then-authorized COVID-19 vaccines. As of November 19, 2021,¹⁴² a single booster dose of each COVID-19 vaccine was authorized for all eligible individuals 18 years of age and older. EUs were subsequently issued for a second booster dose of the Pfizer-BioNTech and Moderna vaccines in certain populations in March 2022.¹⁴⁵

¹³⁸ Food and Drug Administration. February 2021. FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine>.

¹³⁹ Food and Drug Administration. August 2021. FDA Approves First COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

¹⁴⁰ Food and Drug Administration. January 2022. Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

¹⁴¹ Food and Drug Administration. July 2022. Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted>.

¹⁴² Food and Drug Administration. September 2021. FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations. Available at: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations>.

¹⁴³ Food and Drug Administration. October 2021. Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines>.

¹⁴⁴ Food and Drug Administration. November 2021. Coronavirus (COVID-19) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters>.

¹⁴⁵ Food and Drug Administration. March 2022. Coronavirus (COVID-19) Update: FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and>.

FDA first authorized the use of a booster dose of bivalent or “updated” COVID-19 vaccines from Pfizer-BioNTech and Moderna in August 2022.¹⁴⁶

We stated in the CY 2023 ESRD PPS final rule that HCP are at risk of carrying COVID-19 infection to patients, experiencing illness or death themselves as a result of contracting COVID-19, and transmitting COVID-19 to their families, friends, and the general public (87 FR 67244). While the impact of COVID-19 vaccines on asymptomatic infection and transmission is not yet fully known, there is now robust data available on COVID-19 vaccine effectiveness across multiple populations against symptomatic infection, hospitalization, and death. Two-dose COVID-19 vaccines from Pfizer-BioNTech and Moderna were found to be 88 percent and 93 percent effective against hospitalization for COVID-19, respectively, over 6 months for adults over age 18 without immunocompromising conditions.¹⁴⁷ During a SARS-CoV-2 surge in the spring and summer of 2021, 92 percent of COVID-19 hospitalizations and 91 percent of COVID-19-associated deaths were reported among persons not fully vaccinated.¹⁴⁸ Real-world studies of population-level vaccine effectiveness indicated similarly high rates of effectiveness in preventing SARS-CoV-2 infection among frontline workers in multiple industries, with a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.¹⁴⁹

¹⁴⁶ Food and Drug Administration. August 2022. Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>.

¹⁴⁷ Centers for Disease Control and Prevention. September 24, 2021. Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March–August 2021. Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.

¹⁴⁸ Centers for Disease Control and Prevention. September 10, 2021. Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021. Available at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm>.

¹⁴⁹ Centers for Disease Control and Prevention. August 27, 2021. Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021. Available

Continued

Available at: <https://covid.cdc.gov/covid-data-tracker/#data-tracker-home>.

¹³³ U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. 2023. Renewal of Determination that a Public Health Emergency Exists. Available at: <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx>.

¹³⁴ U.S. Dept. of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>.

¹³⁵ Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO-23-02-ALL. October 26, 2022. Available at: <https://www.cms.gov/files/document/qso-23-02-all.pdf>.

¹³⁶ Food and Drug Administration. December 2020. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>.

¹³⁷ Food and Drug Administration. December 2020. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine. Available at: <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid>.

Vaccines have also been highly effective in real-world conditions preventing COVID-19 in HCP with up to 96 percent effectiveness for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID-19.¹⁵⁰ In the presence of high community prevalence of COVID-19, residents of nursing homes with low staff vaccination coverage had higher rates of COVID-19 cases and COVID-19 related deaths than those among residents of nursing homes with high staff vaccination coverage.¹⁵¹ Overall, data demonstrate that COVID-19 vaccines are effective and prevent severe disease, including hospitalization and death.

As SARS-CoV-2 persists and evolves, our COVID-19 vaccination strategy must remain responsive. When we finalized adoption of the COVID-19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, we stated that HCP should be counted as vaccinated if they received COVID-19 vaccination any time from when it first became available in December 2020 (87 FR 67247). We noted that a completed vaccination course, defined for purposes of the measure as the primary vaccination series, may require one or more doses depending on the specific vaccine used, and that the NHSN application automatically calculates the total value for “Any completed COVID-19 vaccine series.” We also stated that, as vaccination protocols continue to evolve, we will continue to work with the CDC to update relevant measure specifications as necessary. Since we finalized the COVID-19 Vaccination Coverage Among HCP measure in the CY 2023 ESRD PPS final rule, new variants of SARS-CoV-2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the CDC because it spreads more easily than earlier variants.¹⁵² Vaccine manufacturers have responded to the Omicron variant by

developing bivalent COVID-19 vaccines, which include a component of the original virus strain to provide broad protection against COVID-19 and a component of the Omicron variant to provide better protection against COVID-19 caused by the Omicron variant.¹⁵³ These booster doses of the bivalent COVID-19 vaccines have been shown to increase immune response to SARS-CoV-2 variants, including Omicron, particularly in individuals who are more than 6 months removed from receipt of their primary series.¹⁵⁴ The FDA issued EUAs for booster doses of two bivalent COVID-19 vaccines, one from Pfizer-BioNTech¹⁵⁵ and one from Moderna,¹⁵⁶ and strongly encourages anyone who is eligible to consider receiving a booster dose with a bivalent COVID-19 vaccine to provide better protection against currently circulating variants.¹⁵⁷ COVID-19 booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination,^{158 159} with a rate of breakthrough infections among HCP who received only a two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.¹⁶⁰ Data from the existing COVID-19 Vaccination Coverage Among HCP

measure demonstrate clinically significant variation in booster dose vaccination rates across facilities.

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID-19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, the continued presence of SARS-CoV-2 in the United States, and variance among rates of booster dose vaccination, it is important to modify the COVID-19 Vaccination Coverage Among HCP measure to reflect recent updates that explicitly specify for HCP to receive primary series and booster vaccine doses in a timely manner. As the COVID-19 pandemic persists, we continue to believe that monitoring and surveillance is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making. We propose to modify the COVID-19 Vaccination Coverage Among HCP measure to replace the term “complete vaccination course” with the term “up to date” in the HCP vaccination definition. We also propose to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID-19 vaccines, including booster doses, beginning with PY 2026. As we stated in the CY 2023 ESRD PPS final rule (87 FR 67245), the COVID-19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates. Unlike outcome measures, process measures do not assess a particular outcome.

b. Overview of Updated Measure

The COVID-19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID-19 vaccination coverage among HCP in settings such as dialysis facilities, and the measure is reported via the CDC’s National Healthcare Safety Network (NHSN).

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67245 through 67246) for more information on the initial review of the measure by the Measure Applications Partnership (MAP). We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022–2023 pre-rulemaking cycle for consideration by the MAP. In December 2022, the MAP’s Hospital Workgroup discussed the modified measure. The Hospital Workgroup stated that the revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations

at: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm>.

¹⁵⁰ Pilishivi, T. et al. (December 2022). Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine*. 2021 Dec 16;385(25):e90. Available online at: <https://pubmed.ncbi.nlm.nih.gov/34551224/>.

¹⁵¹ McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid-19 Outcomes. *New England Journal of Medicine*. 2022 Jan 27;386(4):397–398. Available online at: <https://pubmed.ncbi.nlm.nih.gov/34879189/>.

¹⁵² Food and Drug Administration. August 2021. Variants of the Virus. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html>.

¹⁵³ Food and Drug Administration. November 2022. COVID-19 Bivalent Vaccine Boosters.

¹⁵⁴ Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. *Clin Microbiol Infect*. 2022 May;28(5):735.e1–735.e3. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35143997/>.

¹⁵⁵ Food and Drug Administration. November 2022. Pfizer-BioNTech COVID-19 Vaccines. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines>.

¹⁵⁶ Food and Drug Administration. November 2022. Moderna COVID-19 Vaccines. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines>.

¹⁵⁷ Food and Drug Administration. August 2022. Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>.

¹⁵⁸ Prasad N et al. (May 2022). Effectiveness of a COVID-19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV-2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant—United States, February 14–March 27, 2022. *Morbidity and Mortality Weekly Report (MMWR)*. 2022 May 6;71(18):633–637. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35511708/>.

¹⁵⁹ Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. *Clin Microbiol Infect*. 2022 May;28(5):735.e1–735.e3. Available online at: <https://pubmed.ncbi.nlm.nih.gov/35143997/>.

¹⁶⁰ Ibid.

updated since its initial development. Additionally, the Hospital Workgroup appreciated that the respecified proposed measure of the target population is broader and simplified from seven categories of HCP to four.¹⁶¹ During review, the MAP Health Equity Advisory Group highlighted the importance of COVID–19 measures and asked whether the measure excludes individuals with contraindications to FDA authorized or approved COVID–19 vaccines, and whether the measure will be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but the measure would not be stratified since the data are submitted at an aggregate rather than an individual level. The MAP Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually and that small rural facilities may not have employee health software.¹⁶² The measure developer acknowledged the challenge of getting adequate documentation and emphasized the goal to ensure the measure does not present a burden on the provider. The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID–19 Vaccination Coverage Among HCP measure if vaccination strategy becomes seasonal. The revised measure received conditional support for rulemaking from both the MAP workgroups pending testing indicating the measure is reliable and valid, and endorsement by the consensus-based entity (CBE).¹⁶³ The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636).¹⁶⁴

(1) Measure Specifications

This reporting measure includes at least one week of data collection a

month for each of the three months in a quarter. The denominator would be the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC. Facilities report the following four categories of HCP to NHSN:

1. *Employees*: includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.

2. *Licensed independent practitioners (LIPs)*: This includes physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility but are not directly employed by it (that is, they do not receive a direct paycheck from the reporting facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.

3. *Adult students/trainees and volunteers*: This includes all medical, nursing, or other health professional students, interns, medical residents, and volunteers aged 18 or over who are affiliated with the healthcare facility, but are not directly employed by it (that is, they do not receive a direct paycheck from the facility), regardless of clinical responsibility or patient contact.

4. *Other contract personnel*: Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data for this category are not included in the COVID–19 Vaccination Coverage Among HCP measure.¹⁶⁵

The denominator excludes denominator-eligible individuals with contraindications as defined by the CDC.¹⁶⁶ There are no changes to the denominator exclusions.

The numerator is the cumulative number of HCP in the denominator population who are considered up to

date with recommended COVID–19 vaccines. Facilities should refer to the definition of up to date as of the first day of the applicable reporting quarter, which can be found at <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>. For example, for the proposed updated measure, HCP would be considered up to date during the applicable performance period for the ESRD QIP if they meet one of the following criteria:

1. Individuals who received an updated bivalent¹⁶⁷ booster dose, or
- 2a. Individuals who received their last booster dose less than 2 months ago, or
- 2b. Individuals who completed their primary series¹⁶⁸ less than 2 months ago.

We note that for purposes of NHSN surveillance, the CDC began using this definition of up to date during the quarter 4 2022 surveillance period (September 26, 2022–December 25, 2022).

We refer readers to <https://www.cdc.gov/nhsn/nqf/index.html> for more details on the measure specifications. We note that the proposed updated COVID–19 Vaccination Coverage Among HCP measure will remain a reporting measure and that the proposed updates to measure weighting for PY 2026 and PY 2027 are discussed further in sections IV.C.6 and IV.D.7 of this proposed rule.

(2) Consensus-Based Entity Endorsement

The current version of the measure in the ESRD QIP received CBE endorsement (CBE #3636, “Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel”) on July 26, 2022. Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is

¹⁶¹ Centers for Medicare & Medicaid Services. 2022–2023 Preliminary Analysis Worksheet. 2022. Available at: <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=97891>.

¹⁶² Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

¹⁶³ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

¹⁶⁴ Centers for Medicare & Medicaid Services. 3636 Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel. Accessed February 6, 2023. Available at: <https://www.qualityforum.org/QPS/3636>.

¹⁶⁵ For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID–19 Vaccination Protocol, Weekly COVID–19 Vaccination Module for Healthcare Personnel available at: <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf>.

¹⁶⁶ Centers for Disease Control and Prevention. 2022. Contraindications and precautions. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications>.

¹⁶⁷ The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on 9/2/2022. As of this date, the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

¹⁶⁸ Completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine.

given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. When we adopted this measure in the CY 2023 ESRD PPS final rule, we reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies. The CDC, as the measure developer, is pursuing endorsement for the modified version of the measure.

c. Data Submission and Reporting

We refer readers to the CY 2023 ESRD PPS final rule (87 FR 67246) for information on data submission and reporting for the measure. We are not proposing any changes to the existing data submission requirements.

We invite public comment on this proposal.

4. Proposal To Convert the Clinical Depression Screening and Follow-Up Reporting Measure to a Clinical Measure Beginning With the PY 2026 ESRD QIP

In the CY 2015 ESRD PPS final rule, we finalized the adoption of the Clinical Depression Screening and Follow-Up reporting measure, beginning in PY 2018 (79 FR 66200 through 66203). As we noted in the CY 2015 ESRD PPS final rule, depression is a highly prevalent condition in patients with ESRD, which impacts many aspects of a patient's life and is associated with higher rates of mortality in the ESRD population. Adoption of a measure that assesses whether facilities screen patients for depression, and develop follow-up plans when appropriate, was and still is an opportunity to improve the health of patients with ESRD.

In this proposed rule, we are proposing to convert the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure and to adopt a new methodology for scoring that measure as a clinical measure. We believe this proposal would help to ensure that the measure is scored in a manner that more closely aligns with current clinical guidelines for depression screening and follow-up because it narrows the number of conditions on which a facility can earn points.

Clinical guidelines indicate that providers should both screen for depression and develop a follow-up plan for patients who test positive for depression.¹⁶⁹ Screening for depression is an important aspect of ESRD patient

care, especially because ESRD and depression may present with similar symptoms, including but not limited to fatigue, poor appetite, headaches, and lack of focus.¹⁷⁰ Developing a follow-up plan for patients who screen positive for depression is equally important because ESRD patients may not be aware that they can seek treatment or that such treatment could be beneficial.¹⁷¹ Under the specifications of the current Clinical Depression Screening and Follow-Up reporting measure, facilities are required to report one of six conditions with respect to each eligible patient, and we calculate the measure rate for the facility as the percentage of eligible patients for which the facility reports one of those six conditions. The six conditions are as follows:

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given.
- Screening for clinical depression is documented as negative, and a follow-up plan is not required.
- Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.
- Screening for clinical depression is not documented, and no reason is given.

We are not proposing to revise any of these conditions. However, we are proposing that we would convert the measure to a clinical measure and award credit to facilities only if they report one of the following four of those six conditions:

- Screening for clinical depression is documented as being positive, and a follow-up plan is documented.
- Screening for clinical depression is documented as positive, and a follow-up plan is not documented, and the facility possesses documentation stating the patient is not eligible.

¹⁷⁰ PCORI Evidence Update. Treating Depression When You're on Dialysis (for Patients). July 2021. Available at: <https://www.pcori.org/sites/default/files/PCORI-Evidence-Update-for-Patients-Treating-Depression-When-Youre-on-Dialysis.pdf>.

¹⁷¹ Michael J. Fischer, Elani Streja, Jui-Ting Hsiung, Susan T. Crowley, Csaba P. Kovessdy, Kamyar Kalantar-Zadeh, Wissam M. Kourany, Depression screening and clinical outcomes among adults initiating maintenance hemodialysis, *Clinical Kidney Journal*, Volume 14, Issue 12, December 2021, Pages 2548–2555, <https://doi.org/10.1093/ckj/sfab097>.

• Screening for clinical depression is documented as negative, and a follow-up plan is not required.

• Screening for clinical depression is not documented, but the facility possesses documentation stating the patient is not eligible.

If a facility selects one of the other two conditions (that is, “Screening for clinical depression is documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given” and “Screening for clinical depression is not documented, and no reason is given”), the facility would not receive credit in the numerator. We believe this proposed update is important because it would assess facility performance on both the clinical depression screening and the follow-up plan, to the extent that one is needed, and would also incentivize facilities to report the reason for either not documenting that they screened for clinical depression, or why they do not possess documentation of a follow-up plan. We believe that the performance score calculation methodology changes we are proposing to the Clinical Depression Screening and Follow-Up reporting measure would have a greater impact on fostering care coordination among providers and improving patient outcomes by incentivizing the documentation of depression screenings and follow-up plans, or alternatively requiring facilities to provide a reason why no screening or follow-up plan was documented. This proposed measure update would also align with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.¹⁷² In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.¹⁷³ We are addressing healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to increase efficiency, reduce burden, and close gaps in care. The proposed updates to the Clinical Depression Screening and Follow-Up

¹⁷² Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>.

¹⁷³ Centers for Medicare & Medicaid Services. 2021. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>. We note that Meaningful Measures 2.0 is still under development.

¹⁶⁹ K/DOQI clinical practice guidelines for cardiovascular disease in dialysis patients | Volume 45, SUPPLEMENT 3, 16–153, April 2005. <https://doi.org/10.1053/j.ajkd.2005.01.019>.

measure would support these efforts and would align with several Meaningful Measures Areas, including “Seamless Care Coordination,” and “Behavioral Health,” as we believe that incentivizing the documentation of follow-up plans would encourage care coordination efforts to support the behavioral health outcomes of ESRD patients. The proposed modifications would also align with the Meaningful Measures 2.0 goal to “Leverage measures to drive outcome improvement through public reporting and payment programs” because we believe that converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure would help to drive outcome improvement through the ESRD QIP. Additionally, this proposed measure update would align with efforts to develop a Universal Foundation¹⁷⁴ that would help implement the vision outlined in our National Quality Strategy¹⁷⁵ and is fundamental to achieving several of the agency’s quality and value-based care goals.¹⁷⁶ Our proposal to update the Clinical Depression Screening and Follow-Up reporting measure would help to align the measure that is used in the ESRD QIP with the measure identified for use across multiple programs as part of the Behavioral Health domain of the Universal Foundation measure set.¹⁷⁷

We are also proposing to convert the proposed updated version of the Clinical Depression Screening and Follow-Up measure to a clinical measure beginning with PY 2026, and to move that measure to the Care Coordination Measure Domain beginning with that payment year. We are proposing to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a

clinical measure because we believe that our proposed update to the performance score calculation aligns with that of a clinical measure. We are proposing to move the Clinical Depression Screening and Follow-Up measure from the Reporting Measure Domain to the Care Coordination Measure Domain because the updated clinical measure would no longer be appropriate for inclusion under the Reporting Measure Domain. We note that we are not proposing to change eligibility requirements for the measure. We discuss our proposed updates to measure domains and weights for PY 2026 in section IV.C.6 of this proposed rule.

We welcome public comment on our proposal to update the Clinical Depression Screening and Follow-Up measure and our proposal to convert it to a clinical measure beginning with PY 2026.

5. Proposal To Remove Two Measures From the ESRD QIP Measure Set, Beginning With PY 2026

We have undertaken efforts to review the existing ESRD QIP measure set to ensure continued clinical impact and effectiveness of the measures on facility performance. Based on that analysis and our evaluation of the Program’s measures, we are proposing to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Ratio clinical measure beginning with PY 2026.

a. Proposal To Remove the Ultrafiltration Rate Reporting Measure From the ESRD QIP Measure Set Beginning With PY 2026

In the CY 2017 ESRD PPS final rule, we adopted the Ultrafiltration Rate reporting measure (81 FR 77912 through 77915). The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each qualifying patient. The Ultrafiltration Rate reporting measure is intended to guard against risks associated with high ultrafiltration (that is, rapid fluid removal) rates for adult dialysis patients undergoing hemodialysis (HD), because of indications that high ultrafiltration is an independent predictor of mortality. Faster ultrafiltration may lead to a number of health risks resulting from large volumes of fluid removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term. When we added this measure to the ESRD QIP, we believed the documentation of the ultrafiltration measurements would ultimately contribute to the quality of

the patient’s ESRD treatment (81 FR 77912 through 77915).

More recent studies have indicated that the Ultrafiltration Rate reporting measure may not result in the intended patient outcomes. For example, a patient’s body size may be a confounding, possibly explanatory factor for the relationship between higher UFR and increased mortality.¹⁷⁸ Additionally, although the Ultrafiltration Rate reporting measure captures a patient’s UFR measurements reported monthly, the mortality risks associated with high UFR may be due to the frequency or number of HD sessions with high UFR.¹⁷⁹ We believe these findings show that the documentation of a patient’s ultrafiltration measurements through the current Ultrafiltration Rate reporting measure may not necessarily indicate the quality of a patient’s ESRD treatment and tracking the ultrafiltration rate as a quality indicator may influence decision-making regarding dialysis treatment. Therefore, a facility’s performance on the measure may not accurately reflect the quality of care provided. Accordingly, we are proposing to remove this measure from the ESRD QIP measure set under measure removal factor 2 (performance or improvement on a measure does not result in better or the intended patient outcomes) beginning with the PY 2026 ESRD QIP.

We welcome public comment on our proposal.

b. Proposal To Remove the Standardized Fistula Rate Clinical Measure From the ESRD QIP Measure Set

In the CY 2018 ESRD PPS final rule, we adopted the Standardized Fistula Rate clinical measure (82 FR 50774 through 50777). Along with the Long-Term Catheter Rate clinical measure, we stated that the two vascular access measures, when used together, consider arteriovenous (AV) fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients may exhaust their options for an AV fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all vascular access options. The Standardized Fistula Rate measure adjusts for patient

¹⁷⁴ Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. *The New England Journal of Medicine*, February 1, 2023. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMp2215539>.

¹⁷⁵ Schreiber M, Richards AC, Moody-Williams J, Fleisher LA. The CMS National Quality Strategy: a person-centered approach to improving quality. *Centers for Medicare and Medicaid Services*, June 6, 2022 (<https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>).

¹⁷⁶ Jacobs D, Fowler E, Fleisher L, Seshamani M. The Medicare value-based care strategy: alignment, growth, and equity. *Health Affairs*, July 21, 2022 (<https://www.healthaffairs.org/content/forefront/medicare-value-based-care-strategy-alignment-growth-and-equity>).

¹⁷⁷ Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. *The New England Journal of Medicine*, February 1, 2023. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMp2215539>.

¹⁷⁸ John T. Daugirdas and Daniel Schneditz. *Seminars in Dialysis: Hemodialysis Ultrafiltration Rate Targets Should Be Scaled to Body Surface Area Rather than to Body Weight*. 2017.

¹⁷⁹ Jose E. Navarrete, Ajai Rajabalan, Jason Cobb, and Janice P. Lea. Proportion of Hemodialysis Treatments with High Ultrafiltration Rate and the Association with Mortality. *Kidney* 360 3: 1359–1366, 2022. doi: <https://doi.org/10.34067/KID.0001322022>.

factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option by accounting for that possibility in the current measure specifications. In the CY 2018 ESRD PPS final rule, we stated that this paired incentive structure that relies on both measures reflects consensus best practice and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade (82 FR 50777).

Since the CY 2018 ESRD PPS final rule, there have been several changes to what many experts consider to be best practices with respect to vascular access in ESRD patients due to improvements in the care of ESRD patients overall, changes in patient demographics, and increasing patient longevity. Guidance published in 2019 by the National Kidney Foundation's Kidney Disease Outcome Quality Initiative (KDOQI) reflects updated best practices.¹⁸⁰ The KDOQI's 2019 guidance notes that prior guidelines and initiatives have emphasized a "fistula first" approach to vascular access choice due to the AV fistula's associations with better short-term results compared with other vascular access types.¹⁸¹ However, the 2019 guidance also notes that more recent data have challenged these associations because of the high complication rates of AV fistula maturation failure requiring intervention and increased acceptability of AV grafts. The guidance also encourages a more holistic, long-term approach to dialysis access that strives to preserve patient vasculature and avoid unnecessary procedures and

complications. Therefore, following re-evaluation of this Fistula First approach, the KDOQI's 2019 guidance concludes that the Fistula First approach should no longer be considered a clinical best practice. Instead, the KDOQI's 2019 guidance concludes that a patient-centered approach to dialysis access that is based on a consideration of the patient's needs and individual factors is preferred. Providers should consider what would be most appropriate for the individual patient, including that AV fistula may not always be most appropriate based on the individual patient's needs and goals.

After considering these evolving best practices and the KDOQI's 2019 guidance, we have determined that the Standardized Fistula Rate Clinical Measure does not provide patients and their healthcare providers the necessary level of flexibility to choose the most suitable dialysis access. We believe that patients and their healthcare providers should have the flexibility to choose vascular access (either AV fistula or AV graft) where appropriate to their specific patient characteristics and treatment plans. This determination should be based on the healthcare provider's best clinical judgment that considers the vessel characteristics, patient comorbidities, health circumstances, and patient preference. Accordingly, we are proposing to remove the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026 under measure removal factor 3 (a measure no longer aligns with current clinical guidelines or practice).

We continue to consider both AV fistula and AV graft as preferable forms of vascular access to a long-term catheter, and evidence shows that long-term catheters should only be used when all other AV access options have been exhausted.¹⁸² We also continue to

believe that it is important to track the use of long-term catheters, minimize their use where possible, and incentivize best practices for vascular access. For those reasons, we are not proposing to remove the Long-Term Catheter Rate clinical measure.

We are also proposing to remove the reference to the Vascular Access Type Measure Topic and to assign the total weight of that topic (12 percent) solely to the Long-Term Catheter Rate clinical measure, as described in Table 15 of this proposed rule. We are proposing to assign the total weight to the Long-Term Catheter Rate clinical measure because we believe this continues to be an important measure of facility performance tied to improved patient outcomes. We believe that our proposal to assign the total 12 percent weight to the Long-Term Catheter Rate clinical measure will reflect our view that long-term catheter use is the least-favored vascular access treatment option, and should be avoided where more clinically preferable vascular access treatment options would be appropriate.

We welcome public comment on our proposal.

6. Proposed Revisions To Measure Domains and To Measure Weights Used To Calculate the Total Performance Score (TPS) Beginning With the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS final rule (87 FR 67251 through 67254), we finalized revisions to the ESRD QIP measure domains beginning with PY 2025. Specifically, we added the Reporting Domain and updated measure domains and measure weights across five measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, Safety, and Reporting. The measure domains and weights we finalized in the CY 2023 ESRD PPS final rule are depicted in Table 14 below.

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update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164.

¹⁸⁰ Lok CE, Huber TS, Lee T, et al.; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164.

¹⁸¹ KDOQI clinical practice guidelines for vascular access. Am J Kidney Dis. 2006;48:S176-S247.

¹⁸² Lok CE, Huber TS, Lee T, et al.; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019

TABLE 14: Current PY 2026 ESRD QIP Measure Domains and Weights

Measure/Measure Topics by Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	6.00
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Vascular Access Type Measure Topic	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Clinical Depression Screening and Follow-Up reporting measure	1.67
Hypercalcemia reporting measure	1.67
Ultrafiltration Rate reporting measure	1.67
MedRec reporting measure	1.67
NHSN Dialysis Event reporting measure	1.67
COVID-19 HCP Vaccination reporting measure	1.67

As discussed above, we are proposing that beginning with PY 2026, the Clinical Depression Screening and Follow-Up reporting measure would be converted to a clinical measure and included in the Care Coordination Domain, the Standardized Fistula Rate clinical measure would be removed from the Clinical Care Domain, the Ultrafiltration Rate reporting measure would be removed from the Reporting Domain, and the Facility Commitment to Health Equity reporting measure would be added to the Reporting Domain. To accommodate the new numbers of measures in the Care Coordination Domain, Clinical Care Domain, and Reporting Domain, we are proposing to update the individual measure weights in each of these domains. We believe that these proposed updates to the individual measure weights would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also further incentivizing improvement on clinical measures. For example, for the Care Coordination Domain, we are proposing to update the measure weights for the SHR clinical measure and the SRR clinical measure to accommodate the inclusion of the proposed Clinical Depression Screening and Follow-Up clinical measure. We

believe these newly proposed measure weights would strike an appropriate balance between the importance of facility performance on the SHR clinical measure and the SRR clinical measure on measuring patient outcomes, while also reflecting the impact of the proposed Clinical Depression Screening and Follow-Up clinical measure on patient quality of care. Additionally, the Vascular Access Type Measure Topic is currently weighted at 12 percent and includes both the Standardized Fistula Rate clinical measure and the Long-Term Catheter Rate clinical measure. We are proposing to remove the Standardized Fistula Rate clinical measure and the Vascular Access Type Measure Topic, and we are also proposing to weight the Long-Term Catheter Rate clinical measure at 12 percent. We believe this proposal would incentivize improvement and reflect the impact of facility performance on the Long-Term Catheter Rate clinical measure (as the sole vascular access type measure) on patient outcomes. We continue to believe that patient outcomes improve when they receive the most clinically appropriate vascular access treatment option, and that long-term catheters should only be used when other vascular access treatment options are not feasible. Consistent with our approach in the CY 2023 ESRD PPS

final rule, we are proposing to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (87 FR 67251 through 67253). In light of these proposed updates to measures within the Reporting Measure Domain, we would weight each measure equally at 2 percent, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We note that although we are proposing to change the number of measures in three of the domains and the weights of certain individual measures in those domains, we are not proposing to change the weights of the five domains themselves because we believe the proposed updates to individual measures and measure weights do not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. The previously finalized and newly proposed measures that would be included in each domain, along with the proposed new measure weights, for PY 2026 are depicted in Table 15.

TABLE 15: Previously Finalized and Newly Proposed ESRD QIP Measure Domains and Weights for PY 2026

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	9.00
SRR clinical measure	9.00
PPPW measure	6.00
Clinical Depression Screening and Follow-Up measure*	6.00
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Facility Commitment to Health Equity measure**	2.00
Hypercalcemia reporting measure	2.00
MedRec reporting measure	2.00
NHSN Dialysis Event reporting measure	2.00
COVID-19 HCP Vaccination reporting measure	2.00

*We are proposing to convert the Clinical Depression Screening and Follow-Up measure from a reporting measure to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

**We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

We welcome public comment on these proposals.

7. Performance Standards for the PY 2026 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final

rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (42 CFR 413.178(a)(12)).

In the CY 2023 ESRD PPS final rule (87 FR 67259 through 67260), we set the

performance period for the PY 2026 ESRD QIP as CY 2024 and the baseline period as CY 2022. In this proposed rule, we are estimating the performance standards for the PY 2026 clinical measures in Table 5 using data from CY 2021, which was the most recent data available (87 FR 67260). For certain measures previously suppressed for the PY 2023 performance period due to significant impacts on the measure related to the COVID–19 public health emergency (87 FR 67225 through 67237), we used CY 2019 data. We intend to update these performance standards for all measures, using CY 2022 data, in the CY 2024 ESRD PPS final rule.

TABLE 16: Performance Standards for the Previously Finalized and Newly Proposed ESRD QIP Clinical Measures for PY 2026

Measure	Achievement Threshold (15 th Percentile of National Performance)	Median (50 th Percentile of National Performance)	Benchmark (90 th Percentile of National Performance)
Vascular Access Type (VAT)			
Long-Term Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Standardized Readmission Ratio ^a	34.27	26.97	17.02
NHSN BSI	0.833	0.290	0
Standardized Hospitalization Ratio ^b	187.80	148.33	105.54
Standardized Transfusion Ratio ^b	53.46	29.78	10.75
PPPW	8.12%	16.73%	33.90%
Clinical Depression*	80.95%	91.15%	100.00%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	62.22%	76.57%
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%
*We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning in PY 2026, as discussed in section IV.C.4 of this proposed rule.			

^aRate calculated as a percentage of hospital discharges^bRate per 100 patient-years

Data sources: VAT measures: 2019 EQRS; SRR, SHR: 2019 Medicare claims; STrR: 2021 Medicare claims; Kt/V: 2019 EQRS; Hypercalcemia: 2019 EQRS; NHSN: 2021 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 EQRS and 2019 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2021 EQRS.

In addition, we summarize in Table 17 requirements for successful reporting on previously finalized and newly

proposed reporting measures for the PY 2026 ESRD QIP.

TABLE 17: Requirements for Successful Reporting of the Previously Finalized and Newly Proposed ESRD QIP Reporting Measures for PY 2026

Measure	Reporting Frequency	Data Elements
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: - o physician, - o nurse, - o advanced registered nurse practitioner (ARNP), - o physician assistant (PA), - o pharmacist, or - o pharmacy technician personnel • Name of eligible professional
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 Vaccination Coverage Among HCP*	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received an up to date vaccination course against SARS-CoV-2.
Facility Commitment to Health Equity**	Annually	Domains to which facility must attest affirmatively: • Equity is a Strategic Priority • Data Collection • Data Analysis • Quality Improvement • Leadership Engagement

* We are proposing to update the COVID-19 Coverage Among HCP reporting measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

** We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

8. Eligibility Requirements for the PY 2026 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 18a.

TABLE 18a: Current Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)**	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)***	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)****	N/A	Before September 1 of the performance period that applies to the program year.	N/A

* We are proposing to remove the Standardized Fistula Rate clinical measure beginning in PY 2026, as discussed in section IV.C.5 of this proposed rule, and removed from Table 18b below.

** We are proposing to update the Clinical Depression Screening and Follow-Up measure and convert it to a clinical measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

*** We are proposing to remove the Ultrafiltration Rate reporting measure beginning in PY 2026, as discussed in section IV.C.5 of this proposed rule, and removed from Table 18b below.

**** We are proposing to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

We are proposing to add eligibility requirements for the new measures we

are proposing beginning with the PY 2026 ESRD QIP. Our previously

finalized and proposed new minimum eligibility requirements for scoring the

ESRD QIP measures are described in Table 18b.

TABLE 18b: Previously Finalized and Proposed New Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Clinical)*	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)**	N/A	Before September 1 of the performance period that applies to the program year.	N/A
Facility Commitment to Health Equity (Reporting)***	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	

* We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

** We are proposing to update the COVID-19 Vaccination Coverage Among HCP measure beginning with PY 2026, as discussed in section IV.C.3 of this proposed rule.

*** We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

9. Payment Reduction Scale for the PY 2026 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at 42 CFR 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the

baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Under our current policy, which is codified at 42 CFR 413.177 of our regulations, we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS (76 FR 634 through 635).

For PY 2026, we estimate using available data that a facility must meet or exceed a mTPS of 52 to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2021 and CY 2019 instead of the PY 2026 baseline period (CY 2022) because CY 2022 data are not yet available. We will update and finalize the mTPS and associated payment reduction ranges using CY 2022 data in the CY 2024 ESRD PPS final rule.

TABLE 19: Estimated Payment Reduction Scale for PY 2026 Based on the Most Recently Available Data

<u>Total performance score</u>	<u>Reduction (%)</u>
100-52	0%
51-42	0.5%
41-32	1.0%
31-22	1.5%
21-0	2.0%

D. Proposed Updates to Requirements Beginning With the PY 2027 ESRD QIP

1. PY 2027 ESRD QIP Measure Set

Under our current policy, we generally retain all measures once

adopted for a payment year for subsequent payment years. In this proposed rule, we are proposing to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers

of Health reporting measure to the ESRD QIP measure set beginning with PY 2027.

TABLE 20: Proposed PY 2027 ESRD QIP Measure Set

Consensus-Based Entity (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure Percentage of HCP who receive a complete COVID-19 vaccination course.
N/A	Facility Commitment to Health Equity, a reporting measure Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.
N/A	Screening for Social Drivers of Health, a reporting measure*

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2. Proposal To Adopt the Screening for Social Drivers of Health Reporting Measure Beginning With PY 2027

Our commitment to supporting facilities in building equity into their health care delivery practices is, in part, focused on empowering their workforce to recognize and eliminate health disparities that disproportionately impact their patients who have health-related social needs (HRSNs). HRSNs are significant risk factors associated with worse health outcomes as well as increased health care utilization.¹⁸³ We believe that the identification of HRSNs among facility patients has two significant benefits. First, research has shown that certain HRSNs disproportionately impact populations that have historically been underserved by the healthcare system and screening helps identify individuals who may have HRSNs.¹⁸⁴ Due to the association between chronic condition risk and HRSNs, screening for these needs could serve as evidence-based building blocks for supporting ESRD facilities in addressing persistent disparities and tracking progress towards closing the health equity gap in the ESRD population. Second, we believe HRSN screening by facilities could enable them to engage in meaningful collaboration with other healthcare providers and community-based organizations as part of a more holistic approach to addressing health equity gaps that negatively impact their ESRD patients, which may also eventually result in implementing and evaluating related innovations in health and social care delivery among these facilities, healthcare providers and community-based organizations.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220), we finalized the adoption of two evidence-based measures in the Hospital Inpatient Quality Reporting Program, the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health measures. These two Social Drivers of Health measures support identification of specific risk factors for inadequate

healthcare access and adverse health outcomes among patients. These measures also encourage hospitals to systematically collect HRSN data. We have also finalized a policy requiring that all Special Needs Plans (SNPs) include one or more questions on housing stability, food security, and access to transportation in their Health Risk Assessment (HRA) using questions from a list of screening instruments specified in sub-regulatory guidance (87 FR 27726 through 27740), as well as adopted the Screening for Social Drivers of Health Measure in the Merit-based Incentive Payment System Program (87 FR 70054 and 70055).

Advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars and a Biden-Harris Administration priority.¹⁸⁵ We believe that the proposed Screening for Social Drivers of Health reporting measure aligns with *The CMS Quality Strategy Goals* for effective care coordination and prevention and treatment of chronic conditions.¹⁸⁶ The proposed Screening for Social Drivers of Health reporting measure would enable facilities to identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes. Improvement in risk identification has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to populations with greatest risk, and improve the facility's quality of care through the facility taking steps to mitigate poor health outcomes by improving their care coordination efforts.^{187 188 189 190} These

data could help facilities improve their care coordination efforts, including by understanding what HRSNs might be contributing to poor patient outcomes so that facilities can direct resources, as appropriate, toward referring their patients to resources that might be able to help them resolve their HRSNs.

a. Background

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.^{191 192 193 194 195} Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.^{196 197 198} Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health

¹⁹⁰ Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. Health Affairs Blog, April 19, 2021. Available at: <https://www.healthaffairs.org/doi/10.1377/forefront.20210414.379479/full/>.

¹⁹¹ Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: <https://pubmed.ncbi.nlm.nih.gov/30444684/>.

¹⁹² The Physicians Foundation. 2020. Survey of America's Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

¹⁹³ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

¹⁹⁴ Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

¹⁹⁵ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: <https://doi.org/10.31478/201705b>.

¹⁹⁶ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

¹⁹⁷ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

¹⁹⁸ Khullar, D., MD. 2020, September 8. Association Between Patient Social Risk and Physician Performance American Academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at: https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/team-based-approach.pdf.

¹⁸³ Centers for Medicare & Medicaid Services. 2021. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>. Accessed: November 23, 2021.

¹⁸⁴ American Hospital Association. 2020. Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.

¹⁸⁵ Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms>.

¹⁸⁶ Centers for Medicare & Medicaid Services. (2021) CMS National Quality Strategy. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>

¹⁸⁷ Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: <https://doi.org/10.1377/hlthaff.2020.01742>.

¹⁸⁸ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: <https://doi.org/10.1161/CIRCOUTCOMES.120.006752>.

¹⁸⁹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

outcomes.^{199 200 201} Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.^{202 203}

Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD.^{204 205} The COVID-19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and health care utilization in the United States.^{206 207} Emerging evidence has shown that specific social risk factors are directly associated with health outcomes and health care utilization and costs.^{208 209 210 211} Of particular concern

among people with ESRD are HRSNs that have an effect on treatment outcomes, including inadequate access to healthy foods, unstable housing, limited transportation, and community safety concerns.^{212 213}

We believe that improvement in care coordination between ESRD facilities, hospitals, and community-based organizations would yield better health outcomes for people with ESRD, and subsequently lead to improvements in quality performance for dialysis and other health care providers. We believe that the proposed Screening for Social Drivers of Health reporting measure would help inform facilities of the impact of HRSNs in people with ESRD by assessing the proportion of adult patients who are screened for social drivers of health in five core domains: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

In the CY 2023 ESRD PPS proposed rule, we sought public comment on the potential future inclusion of the Screening for Social Drivers of Health measure (87 FR 38554 through 38556) in the ESRD QIP. For a summary of the comments we received, as well as our responses, we refer readers to the CY 2023 ESRD PPS final rule (87 FR 67265 through 67268). In the CY 2023 ESRD PPS final rule, we stated that we were considering whether to incorporate measures that assess screening for health-related social needs into the ESRD QIP measure set (87 FR 67264).

We are proposing to adopt the Screening for Social Drivers of Health reporting measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP. As discussed above, disparities in health equity are tied to worse patient outcomes in the ESRD community. While widespread interest in addressing HRSNs exists, action is inconsistent, specifically in ESRD facilities.

Therefore, we believe it is appropriate to require facilities to report data on this measure because the intent of the proposed measure is to incentivize facilities to collect and utilize their data to identify the impact of HRSNs in their ESRD patient population, including whether there is a relationship between those HRSNs and the outcomes experienced by their patients with those HRSNs. Screening data collected by the facility could inform their provision of care such that they improve the outcomes experienced by patients with HRSNs. Facilities could analyze their screening data to understand whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. While the measure does not require facilities to take specific actions following an HRSN screening, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the proposed measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a state's civil rights laws.

Under our Meaningful Measures Framework,²¹⁴ the Screening for Social Drivers of Health reporting measure, along with the Screen Positive Rate for Social Drivers of Health reporting measure discussed in section IV.D.3 of this proposed rule, addresses the quality priority of "Work with Communities to Promote Best Practices of Healthy Living" through the Meaningful Measures Area of "Equity of Care." Additionally, consistent with Meaningful Measures 2.0, these measures address the "healthcare equity" priority area and align with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to "develop and implement measures that reflect social and economic determinants."²¹⁵ Development and proposal of these measures also aligns with our strategic pillar to advance health equity by addressing the health

¹⁹⁹ Institute of Medicine. 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/18951>.

²⁰⁰ Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²⁰¹ Centers for Disease Control and Prevention. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html>. Accessed November 17, 2021.

²⁰² Zhang Y, Li J, Yu J, Braun RT, Casalino LP. 2021. Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*. 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

²⁰³ Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975–983. <https://doi.org/10.1001/jama.2020.13129>.

²⁰⁴ United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

²⁰⁵ Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al. (2021). Initial Effects of COVID-19 on Patient with ESKD. *Journal of the American Society of Nephrology* 32: 1444–1453. doi: <https://doi.org/10.1681/ASN.2021010009>.

²⁰⁶ Centers for Disease Control. CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity. July 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html>. Accessed November 17, 2021.

²⁰⁷ Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al. (2021). Initial Effects of COVID-19 on Patient with ESKD. *Journal of the American Society of Nephrology* 32: 1444–1453. doi: <https://doi.org/10.1681/ASN.2021010009>.

²⁰⁸ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053>.

²⁰⁹ Dean, E.B., French, M.T., Mortensen, K. (2020). *Health Services Research* 55 (Supplement 2): 883–893. doi:10.1111/1475-6773.13283.

²¹⁰ Berkowitz, S.A., Kalkhoran, S., Edwards, S.T., Essien, U.R., Baggett, T.P. (2018). Unstable Housing and Diabetes-Related Emergency Department Visits and Hospitalization: A Nationally Representative Study of Safety-Net Clinic Patients. *Diabetes Care* 41: 933–939. <https://doi.org/10.2337/dc17-1812>.

²¹¹ National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25385>.

²¹² *Ibid*.

²¹³ CMS (2021). *Chronic Kidney Disease Disparities: Educational Guide for Primary Care*. Available at: <https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf>.

²¹⁴ Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiatives-GenInfo/CMS-Quality-Strategy>.

²¹⁵ Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>. We note that Meaningful Measures 2.0 is still under development.

disparities that underlie our health system.²¹⁶ We also believe these measures would address the quality priority “Promoting Effective Prevention and Treatment of Chronic Disease” through the Meaningful Measures Area “Management of Chronic Conditions,” by improving a facility’s ability to assess and implement effective care coordination for its patients. For example, data demonstrate that an overwhelming majority of people with ESRD travel outside their homes for dialysis three times per week, round trip, and that transportation challenges contribute to shortened treatment episodes and adverse health outcomes.^{217 218} Identification of patients with transportation difficulties could encourage facilities to provide information to these patients about available community-based transportation services that could help these patients with their transportation needs. We also believe that the proposed measures would encourage facilities to incorporate HRSN screening into their routine care, which would in turn improve their ability to understand the full needs of their patients, including those who may need additional care coordination but might be reluctant to otherwise seek assistance due to concerns about personal stigmatization.

Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.^{219 220} In 2017, CMS’s Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of community-dwelling Medicare and Medicaid beneficiaries (through screening,

referral, and community navigation on their health outcomes and related healthcare utilization and costs).^{221 222 223 224} The CMS Innovation Center developed the AHC Model based on evidence that addressing HRSNs through enhanced linkages between health systems and community-based organizations can improve health outcomes and reduce costs.²²⁵ HRSNs are significant risk factors associated with adverse health outcomes and increased health care utilization, including excessive emergency department (ED) visits and avoidable hospitalizations.^{226 227} Unmet HRSNs, such as food insecurity, inadequate or unstable housing, and inadequate transportation may increase risk for onset of chronic conditions, such as ESRD, and accelerate exacerbation of related adverse health outcomes.^{228 229 230} The AHC Model had

a 5-year period of performance that began in May 2017 and concluded in April 2022, with beneficiary screening beginning in the summer of 2018 following an implementation period.^{231 232} Evaluation of the AHC Model data is still underway, and the most recent evaluation was published in the second AHC Model evaluation report on May 18, 2023.²³³

While social risk factors may have a significant impact on health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.^{234 235 236 237} The persistent interactions between individuals’ HRSNs, medical providers’ practices/ behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare.^{238 239} In

²³⁰ Laraia, B.A. (2013). Food Insecurity and Chronic Disease. *Advances in Nutrition*, 4: 203–212, doi:10.3945/an.112.003277.

²³¹ RTI International. 2020. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt>.

²³² We note that the model officially concluded in April 2022 but many awardees are continuing with no-cost extensions to continue utilizing unspent cooperative agreement funding and all awardees will conclude by April 2023.

²³³ RTI International. 2023. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2023/ahc-second-eval-rpt>.

²³⁴ Kaiser Family Foundation. 2021. Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>. Accessed November 23, 2021.

²³⁵ Khullar, D., MD. 2020, September 8. Association Between Patient Social Risk and Physician Performance. *American Academy of Family Physicians*. 2020. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.

²³⁶ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. *Circulation: Cardiovascular Quality and Outcomes*, 13 (6) 290–299. Available at: <https://doi.org/10.1161/CIRCOUTCOMES.120.006752>.

²³⁷ The Physicians Foundation. 2021. Viewpoints: Social Determinants of Health. Available at: <https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf>. Accessed December 8, 2021.

²³⁸ Centers for Medicare & Medicaid Services. 2021. Paving the Way to Equity: A Progress Report. Accessed January 18, 2022. Available at: <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>.

²³⁹ Centers for Medicare & Medicaid Services Office of Minority Health. 2021. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf#:~:text=The%20Centers%20for%20Medicare%20and%20Medicaid%20Services%20and%20CMS%29,evidence%20base%2C%20identifying%20opportunities%2C%20and%20gathering%20stakeholder%20input.

²¹⁶ Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms>.

²¹⁷ Ibid.

²¹⁸ United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

²¹⁹ Zhang Y, Li J, Yu J, Braun RT, Casalino LP. 2021. Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*. 2021;4(6):e2113212. doi:10.1001/jamanetworkopen.2021.13212.

²²⁰ Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975–983. <https://doi.org/10.1001/jama.2020.13129>.

²²¹ Centers for Medicare & Medicaid Services. 2021. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

²²² Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²²³ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²²⁴ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: <https://innovation.cms.gov/innovation-models/ahcm>.

²²⁵ RTI International. 2020. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt>.

²²⁶ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²²⁷ Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²²⁸ Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

²²⁹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053>.

their 2018 survey of 8,500 physicians, The Physicians Foundation found almost 90 percent of physician respondents reported their patients had a serious health problem linked to poverty or other social conditions.²⁴⁰ Additionally, associations between disproportionate health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID–19 pandemic.^{241 242}

The following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries under the AHC Model: (1) food insecurity; (2) housing instability; (3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: (1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; (2) ability for a given HRSN to be screened and identified in the inpatient setting prior to hospital discharge, addressed by community-based services, and potentially improve healthcare outcomes, including reduced hospital re-admissions; and (3) evidence that a given HRSN is not systematically addressed by healthcare providers.²⁴³ In addition to established evidence of their association with health status, risk, and outcomes, these five domains were also selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.^{244 245 246}

These five evidence-based HRSN domains informed our development of the proposed Screening for Social Drivers of Health reporting measure, as well as a second measure, Screen Positive Rate for Social Drivers of Health reporting measure, that we are also proposing to adopt for the ESRD QIP. These domains are described in Table 21.

TABLE 21: Five Core HRSN Domains Used in the Screening for Social Drivers of Health Reporting Measure and the Screen Positive Rate for Social Drivers of Health Reporting Measure

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions. ^{247,248} Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence. ^{254,255} Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing unstable housing. ²⁵⁶ Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services. ^{257,258}
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living. ²⁵⁹ Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and

²⁴⁰ The Physicians Foundation. 2019. Viewpoints: Social Determinants of Health. Available at: <https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf>. Accessed December 8, 2021.

²⁴¹ Centers for Disease Control and Prevention. 2020. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html>. Accessed November 17, 2021.

²⁴² Kaiser Family Foundation. 2021. Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>. Accessed November 23, 2021.

²⁴³ Billieux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁴⁴ Billieux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁴⁵ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: <https://innovation.cms.gov/innovation-models/ahcm>.

²⁴⁶ Kamyck, D., Senior Director of Marketing. 2019. CMS releases standardized screening tool for health-related social needs. Activate Care. Available at: <https://blog.activatecare.com/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/>.

Domain	Description
	more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations. ^{260,261,262,263}
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity. ²⁶⁴ Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements. ²⁶⁵
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse. ²⁶⁶ Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups. ^{267,268}

The proposed Screening for Social Drivers of Health reporting measure assesses screening of the same HRSNs.

²⁴⁷ Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. *Am J Managed Care*. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

²⁴⁸ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁴⁹ Seligman, H.K. & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. *Annual Review of Public Health*, 40(1), 319–337. Available at: <https://pubmed.ncbi.nlm.nih.gov/30444684/>.

²⁵⁰ National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23285>.

²⁵¹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁵² Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. *Am J Managed Care*. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

²⁵³ Dean, E.B., French, M.T., & Mortensen, K. (2020a). Food insecurity, health care utilization, and health care expenditures. *Health Services Research*, 55(S2), 883–893. Available at: <https://doi.org/10.1111/1475-6773.13283>.

²⁵⁴ Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. *JAMA*, 301(13), 1349. Available at: <https://doi.org/10.1001/jama.2009.414>.

²⁵⁵ Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁵⁶ Henry, M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

²⁵⁷ Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. *JAMA*, 301(13), 1349. Available at: <https://doi.org/10.1001/jama.2009.414>.

²⁵⁸ Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379–387. Available at: <https://jech.bmj.com/content/jech/73/5/379.full.pdf>.

²⁵⁹ National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23285>.

²⁶⁰ National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23285>.

²⁶¹ Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*. Available at: <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

²⁶² Billieux, A., Verlander, Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁶³ Shier, G., Ginsburg, M., Howell, J., Volland, P., & Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. *Health Affairs*, 32(3), 544–551. Available at: <https://doi.org/10.1377/hlthaff.2012.0170>.

²⁶⁴ Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379–387. Available at: <https://jech.bmj.com/content/jech/73/5/379.full.pdf>.

²⁶⁵ Wright, B.J., Vartanian, K.B., Li, H.F., Royal, N., & Matson, J.K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. *Health Affairs*, 35(1), 20–27. Available at: <https://doi.org/10.1377/hlthaff.2015.0393>.

²⁶⁶ Billieux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁶⁷ Henry, M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

We are proposing that facilities would be able to choose a screening tool for purposes of this measure or otherwise screen their patients using a method of their choosing in order to give facilities the flexibility to accommodate the population they serve and their individual needs.^{269 270} We note that the 10-item AHC Health-Related Social Needs Screening Tool that AHC Model participants used to identify HRSNs in the five core domains (described in Table 21) among community-dwelling Medicare, Medicaid, and dually eligible beneficiaries was tested across varied care-delivery sites in diverse geographic locations across the U.S.^{271 272} Facilities may wish to consider using that tool because it has been found to be both reliable and valid, including high inter-rater reliability and concurrent and predictive validity.²⁷³ Moreover, the

²⁶⁸ Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. *JAMA*, 301(13), 1349. Available at: <https://doi.org/10.1001/jama.2009.414>.

²⁶⁹ Social Interventions Research & Evaluation Network. 2019. Social Needs Screening Tool Comparison Table. Available at: <https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison>. Accessed January 18, 2021.

²⁷⁰ Centers for Medicare & Medicaid Services. 2021. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>. Accessed January 18, 2021.

²⁷¹ More information on the HRSN Screening Tool is available at: <https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf>.

²⁷² RTI International. 2020. Accountable Health Communities (AHC) Model Evaluation. Available at: <https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt>.

²⁷³ Lewis C., Wellman R., Jones S., Walsh-Bailey C., Thompson E., Derus A., Paolino A., Steiner J., De Marchis E., Gottlieb L., and Sharp A. (2020). Comparing the Performance of Two Social Risk Screening Tools in a Vulnerable Subpopulation. *J Family Med Prim Care*. 2020 Sep; 9(9): 5026–5034. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/>.

screening tool can be implemented in a variety of places where patients seek healthcare, including dialysis facilities.²⁷⁴ However, as stated above, we are not proposing to require facilities to use this tool, or any other specific tool, for purposes of the proposed Screening for Social Drivers of Health reporting measure.

b. Overview of Measure

The Screening for Social Drivers of Health measure would assess the percentage of patients age 18 and older that a dialysis facility screens for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, facilities would provide: (1) the number of patients admitted to the facility who are 18 years or older during the applicable performance period who are screened for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety; and (2) the total number of patients at the facility who are 18 years or older during the applicable performance period and who are not excluded from the measure. We are proposing to add this measure to the Reporting Measure Domain beginning

with PY 2027. We discuss our proposed updates to measure domains and weights for PY 2027 in section IV.D.7 of this proposed rule.

Measure specifications for this proposed measure are currently available on the QualityNet website at: <https://qualitynet.cms.gov/esrd/esrdqip>.

(1) Cohort

The cohort for the proposed Screening for Social Drivers of Health reporting measure is all patients, aged 18 years and older, who are treated at the facility during the applicable performance period and not eligible to be excluded from the measure.

(2) Numerator

The numerator is calculated as the number of patients who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened during the performance period for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

(3) Denominator

The denominator is calculated as the number of patients at the dialysis

facility and who are 18 years or older on the first day of the performance period. The following patients would be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are unable to complete the screening and have no legal guardian or caregiver who is able to complete the screening on their behalf.

c. Measure Calculation

The Screening for Social Drivers of Health measure would be calculated as the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened by the facility for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the 1st day of the performance period (January 1st) at that dialysis facility. We are proposing a 12-month period of performance for the measure, and facilities would be required to report annually. We are proposing that a facility would be scored according to the following equation:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Screened for all Five HRSNs During the Performance Period}}{\text{Total Number of Eligible Patients During the Performance Period}} \right] \times 10$$

We believe that this scoring policy would encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be based on circumstances beyond a facility's control.

d. Data Submission and Reporting

We are proposing that facilities would report this measure on an annual basis beginning with PY 2027. In alignment with the policy we finalized for the Hospital IQR Program, we are proposing that facilities would be able to select their own screening tool or method to screen patients for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Potential sources of these data for incorporation in a tool

could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. Additionally, multiple screening tools exist and are publicly available. Facilities could refer to the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools.²⁷⁵ SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions. We would encourage facilities to consider digital standardized screening tools and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207), where we

noted that the use of certified health IT can support capture of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care.

We are proposing that the deadline for submission would be the end of the EQRS December data reporting month for the applicable performance period, which is consistent with current reporting deadlines for other ESRD QIP measures. For example, the deadline for submission in PY 2027 would be the end of the December data reporting month in CY 2025.

e. Review by the Measure Applications Partnership

We included the Screening for Social Drivers of Health reporting measure as a measure under consideration for the

²⁷⁴ CMS. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

²⁷⁵ Social Interventions Research & Evaluation Network. 2019. Social Needs Screening Tool Comparison Table. Available at: <https://sirennetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison>. Accessed January 18, 2021.

²⁷⁶ The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on the social determinants of health and healthcare delivery.

ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.²⁷⁷ The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Screening for Social Drivers of Health measure (MUC 2022–053) in detail and at the same time as the Screen Positive Rate for Social Drivers of Health measure on December 6–7, 2022 (discussed below).²⁷⁸ The Health Equity Advisory Group expressed support for the data collection related to social drivers of health, but raised concerns about public reporting of the data and redundancy in asking for the same information of patients. In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and the MAP Hospital Workgroup did so on December 13–14, 2022.²⁷⁹ The Rural Health Advisory Group noted some potential reporting

challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but expressed that the measure serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue. The MAP Hospital Workgroup members conditionally supported the measure pending: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.²⁸⁰ Thereafter, the MAP Coordinating Committee deliberated on January 24–25, 2023, and ultimately voted to conditionally support the Screening for Social Drivers of Health reporting measure for rulemaking with the same conditions.²⁸¹

²⁷⁷ Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. Available at: <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>.

²⁷⁸ Centers for Medicare & Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations. Health Equity Advisory Group. Available at: <https://www.qualityforum.org/ProjectMaterials.aspx?projectID=95514>.

²⁷⁹ Centers for Medicare & Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations, Rural Health Advisory Group. Available at https://www.qualityforum.org/MAP_Rural_Health_Advisory_Group.aspx and MAP Hospital Workgroup. Available at: https://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

²⁸⁰ Centers for Medicare & Medicaid Services. (2022). 2022–2023 MAP Final Recommendations. Available at <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=98102>. For information on the GRAVITY project, please see <https://thegravityproject.net/>.

²⁸¹ Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022–2023–MAP-Final-Recommendations-508.xlsx>.

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

We are proposing to publicly display the facility-specific results for the Screening for Social Drivers of Health measure on an annual basis through our *Care Compare* website at: <https://www.medicare.gov/care-compare/>. We anticipate making the first public report available in January 2027.

We invite public comment on this proposal.

3. Proposal To Adopt the Screen Positive Rate for Social Drivers of Health Reporting Measure Beginning With PY 2027

a. Background

The impact of social risk factors on health outcomes has been well-established in the literature.^{282 283 284 285 286} The Physicians Foundation reported that 73 percent of the physician respondents to their annual survey agreed that social risk factors such as housing instability and food insecurity would drive health services demand in 2021.²⁸⁷ Recognizing the need for a more comprehensive approach to closing equity gaps, we have prioritized quality measures that identify social drivers of health among patients served in various care settings and, in turn, support providers in addressing the impact of these drivers on disparities in patient outcomes, healthcare utilization, and costs.^{288 289 290} Specifically, in the

dialysis facility setting, we aim to encourage systematic identification of patients' HRSNs as part of treatment planning, with the intention of promoting linkages with relevant community-based services that address those needs. We also believe that the identification of HRSNs can help facilities devise strategies that improve the quality of care provided to all of their patients and lead to improved health outcomes following establishment of care at the facility.

While the proposed Screening for Social Drivers of Health reporting measure (discussed in section IV.D.2 of this proposed rule) enables facilities to identify patients with HRSNs, the Screen Positive Rate for Social Drivers of Health measure would allow facilities to capture the magnitude of these needs by reporting the rate of those patients who screen positive for HRSNs and even potentially estimate the impact of individual-level HRSNs on healthcare utilization when evaluating quality of care.^{291 292 293} These measures complement each other because they would require facilities to report both the percentage of patients they screened (under the proposed Screening for Social Drivers of Health measure) and the results of that screening (under the proposed Screen Positive Rate for Social Drivers of Health measure) in order to potentially identify gaps and develop sustainable solutions at a facility level and a community level. We note that our proposals to adopt these two separate, complementary measures align with other quality reporting programs. These two measures have been finalized for the Hospital Inpatient Quality Reporting Program in the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) final rule (87 FR 49191 through 49220), and are currently proposed for the PPS-Exempt Cancer

Hospital Quality Reporting Program in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27122 through 27130) and the Inpatient Psychiatric Facility Quality Reporting Program in the FY 2024 IPF PPS proposed rule (88 FR 21279 through 21288).

We are proposing to adopt this proposed measure under section 1881(h)(2)(A)(iv) of the Act, which gives the Secretary broad authority to specify measures for the ESRD QIP. The Screen Positive Rate for Social Drivers of Health reporting measure would require facilities to screen all patients who are 18 years or older for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety and then report the resulting screen positive rates for each of those domains to CMS. These are the same five core HRSN domains that facilities would be required to screen for under the proposed Screening for Social Drivers of Health reporting measure, and facilities could use the same screening tool for purposes of both measures. Reporting the screen positive rate for social drivers of health for each domain could inform actionable planning by facilities by helping to enable the development of individual patient action plans for those patients who screen positive (including navigation and referral). Following a positive HRSN screening, facilities could analyze data to understand, for example, whether there are any HRSNs that may be affecting their patients' access to care or contributing to poor outcomes in their patient populations and, in turn, develop appropriate solutions to improve access and outcomes. Thus, this measure has the potential to improve patient outcomes by acknowledging patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes and providing the opportunity for additional support by linking providers with community-based organizations to enhance patient-centered treatment and discharge planning, although such reach out is not required.^{294 295 296} This measure may also prove useful to

²⁸² Institute of Medicine 2014. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/18951>.

²⁸³ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: <https://innovation.cms.gov/innovation-models/ahcm>. Accessed November 23, 2021.

²⁸⁴ Kaiser Family Foundation. 2021. Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>. Accessed November 23, 2021.

²⁸⁵ Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, *Journal of Women's Health* 26(6) (2016) at 58; Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. *Health Psychology*, 35(4), 351–355. <https://doi.org/10.1037/hea0000268>.

²⁸⁶ Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2020. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

²⁸⁷ The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

²⁸⁸ Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *The New England Journal of Medicine* 374(1):8–11. Available at: <https://doi.org/10.1056/NEJMp1512532>.

²⁸⁹ Centers for Medicare & Medicaid Services. 2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: <https://innovation.cms.gov/innovation-models/ahcm>. Accessed November 23, 2021.

²⁹⁰ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The

Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). Available at: <https://doi.org/10.31478/201705b>.

²⁹¹ Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. *Health Affairs*, 40(4), 645–654. Available at: <https://doi.org/10.1377/hlthaff.2020.01742>.

²⁹² CMS. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: <https://innovation.cms.gov/innovation-models/ahcm>. Accessed November 23, 2021.

²⁹³ Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. *Circulation: Cardiovascular Quality and Outcomes*, 13 (6) 290–299. Available at: <https://doi.org/10.1161/CIRCOUTCOMES.120.006752>.

²⁹⁴ The Physicians Foundation. 2020. Survey of America's Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

²⁹⁵ De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. *The Journal of the American Board of Family Medicine*, 32 (1), 69 through 78.

²⁹⁶ Kung, A., Cheung, T., Knox, M., Willard-Grace, R., Halpern, J., et al. (2019). Capacity to Address Social Needs Affect Primary Care Clinician Burnout. *Annals of Family Medicine*. 17 (6), 487 through 494. Available at: <https://doi.org/10.1370/afm.2470>.

patients by providing data transparency and signifying facilities' familiarity, expertise, and commitment regarding these issues. Finally, we believe this measure has the potential to facilitate data-informed collaboration with community-based services and focused community investments, including the development of pathways and infrastructure to more seamlessly connect patients to local community resources. Thus, the measure aims to support facilities in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of their resources. While the measure does not require facilities to take specific actions, we expect that any solution a facility might develop to address a gap it identifies would comply with all applicable Federal non-discrimination laws. We also note that the proposed measure is intended to promote health equity for all patients and is not intended to create a conflict between a CMS requirement and a state's civil rights laws.

b. Overview of Measure

The Screen Positive Rate for Social Drivers of Health measure would identify the proportion of patients at the facility who screened positive for each of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. We would

require facilities to report these data as five separate rates.²⁹⁷ We refer readers to section IV.D.2 of this proposed rule where we discussed our process for identifying these five domains, which we are also proposing to use for the proposed Screening for Social Drivers of Health reporting measure.

Measure specifications for this measure are currently available on the QualityNet website at: <https://qualitynet.cms.gov/esrd/esrdqip>.

(1) Cohort

The cohort for the Screen Positive Rate for Social Drivers of Health is a process measure that would provide information on the percentage of patients, aged 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened by the facility for an HRSN, and who screened positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.

(2) Numerator

The numerator would consist of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, who were screened for an HRSN, and for whom the facility reports the results of a screen asking whether

they have a need in one or more of the following five HRSNs (calculated separately): Food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.

(3) Denominator

The denominator would consist of the number of patients at a dialysis facility who are 18 years or older who are treated at the facility during the applicable performance period and are not eligible to be excluded from the measure, and are screened for an HRSN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety). The following patients would be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening and have no caregiver able to do so on the patient's behalf.

c. Measure Calculation

The facility's measure rate for this measure would be calculated for a payment year as the number of eligible patients for whom the facility reports the screening results for all five HRSNs during the performance period over the total number of eligible patients who the facility screened for all five HRSNs during that performance period. To calculate the facility's score on the measure, we would multiply the results of that fraction by ten. The full equation is set forth here:

$$\left[\frac{\text{Number of Eligible Patients for Whom a Facility Reports Screening Results for all Five HRSNs During the Performance Period}}{\text{Total Number of Eligible Patients who were Screened for all Five HRSNs During the Performance Period}} \right] \times 10$$

However, for purposes of public reporting only, we are proposing to display the facility's screen positive rate for each HRSN separately, for a total of five separate rates. Although we will not score facilities on the results of those five separate rates, we believe that making such data public may help to better inform patients and their caregivers about a facility. We are proposing a 12-month period of performance for the measure, and facilities would be required to report annually.

We believe that these policies would encourage facilities to report the measure data appropriately without scoring facilities based on the results of

such data, which may be based on circumstances beyond a facility's control. Although we believe that it is important to encourage facilities to screen their patients for HRSNs and to report data for screen positive rates, we want to avoid potential unintended consequences that may result from scoring facilities on the outcomes of the screen positive rates themselves. That is, we do not want to score a facility based on its patients' given socioeconomic factors, which may be based on circumstances beyond a facility's control.

d. Data Collection, Submission and Reporting

We are proposing that facilities would be required to submit data necessary to calculate the numerator and the denominator for this measure once annually within the ESRD Quality Reporting System (EQRS), beginning with PY 2027. We are proposing that facilities would be required to submit data on this proposed measure using the same process we have finalized for the submission of data on other measures in the ESRD QIP within EQRS.

²⁹⁷ Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-

Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool.

NAM Perspectives, 7(5). Available at: <https://doi.org/10.31478/201705b>.

e. Review by the Measure Applications Partnership

We included the Screen Positive Rate for Social Drivers of Health reporting measure for consideration in the ESRD QIP on the publicly available 2022 MUC List, a list of measures under consideration for use in various Medicare programs.²⁹⁸ The CBE-convened MAP Health Equity Advisory Group reviewed the Screen Positive Rate for Social Drivers of Health measure (MUC 2022–050) in detail and at the same time as the Screening for Social Drivers of Health measure on December 6–7, 2022.²⁹⁹ The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting and the repetition of asking patients the same questions. In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and was also reviewed by the MAP Hospital Workgroup on December 13–14, 2022.³⁰⁰ The Rural Health Advisory Group noted potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but also expressed support that the measure seeks to advance the drivers of health and serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup recommended conditional support for the measure for rulemaking pending endorsement by a CBE to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across dialysis facilities).³⁰¹ Thereafter, the

MAP Coordinating Committee deliberated on January 24–25, 2023, and ultimately voted to conditionally support the Screen Positive Rate for Social Drivers of Health measure for rulemaking with the same conditions.³⁰²

f. Consensus-Based Entity Endorsement

Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1881(h)(2)(B)(ii) of the Act applies.

g. Public Display

We are proposing to publicly display the ESRD QIP score and facility-specific rates for the Screen Positive Rate for Social Drivers of Health measure on an annual basis beginning in PY 2027 through our *Care Compare* website at: <https://www.medicare.gov/care-compare/>.

We invite public comment on this proposal.

4. Performance Period for the PY 2027 ESRD QIP

We continue to believe that our current policy of 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2025 as the performance period and CY 2023 as the baseline period for the PY 2027 ESRD QIP.

We are not proposing any changes to this policy.

5. Performance Standards for the PY 2027 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP

for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively. For reporting measures, performance standards are the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure (42 CFR 413.178(a)(12)).

a. Performance Standards for Clinical Measures in the PY 2027 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we do not have CY 2022 data. We intend to publish these numerical values, using CY 2022 data, in the CY 2024 ESRD PPS final rule.

b. Proposed Performance Standards for the Newly Proposed Reporting Measures Beginning With the PY 2027 ESRD QIP

We are proposing to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with the PY 2027 ESRD QIP, which we discuss in IV.D.2 and IV.D.3 of this proposed rule. We are proposing a 12-month period of performance for both the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure, and facilities would be required to report annually for both measures beginning with the PY 2027 ESRD QIP.

6. Scoring the PY 2027 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this

²⁹⁸ Centers for Medicare & Medicaid Services. 2022. List of Measures Under Consideration for December 1, 2022. Available at: <https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx>.

²⁹⁹ Centers for Medicare & Medicaid Services. 2022. 2022–2023 MAP Preliminary Recommendations, Health Equity Advisory Group. Available at: <https://www.qualityforum.org/ProjectMaterials.aspx?projectID=95514>.

³⁰⁰ Centers for Medicare & Medicaid Services. 2022. MAP Preliminary Recommendations, Rural Health Advisory Group. Available at https://www.qualityforum.org/MAP_Rural_Health_Advisory_Group.aspx; See also, MAP Hospital Workgroup. Available at: https://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.

³⁰¹ Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

³⁰² Centers for Medicare & Medicaid Services. 2023. 2022–2023 MAP Final Recommendations. Available at: <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

methodology for future payment years (83 FR 57011) and we codified these scoring policies at 42 CFR 413.178(e). In the CY 2023 ESRD PPS final rule, we updated our scoring methodology beginning with PY 2025 (87 FR 67251 through 67254).

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at 42 CFR 413.178(e). In section IV.D.2 of this proposed rule, we are proposing to adopt the Screening for Social Drivers of Health reporting measure beginning with PY 2027. We are also proposing to adopt the Screen Positive Rate for Social Drivers of Health reporting measure, as discussed in section IV.D.3 of this proposed rule. We are proposing that a facility would be scored based on the equations proposed in sections IV.D.2.c and IV.D.3.c of this proposed rule. We are proposing a 12-month period of performance for the measures, and facilities would be required to report annually. We believe that these scoring policies would encourage facilities to report the measure data appropriately without penalizing facilities for the results of such data, which may be

impacted by circumstances beyond a facility's control.

7. Proposed Revisions To Measure Domains and To Measure Weights Used To Calculate the Total Performance Score (TPS) Beginning With the PY 2027 ESRD QIP

Beginning with PY 2027, we are proposing to add the Screening for Social Drivers of Health reporting measure and the Screen Positive for Social Drivers of Health reporting measure to the Reporting Measure Domain. To accommodate the new number of measures in the Reporting Measure Domain, we are proposing to update the individual measure weights in this domain. We believe that these proposed updates would help to ensure that a facility's individual measure performance has an appropriately proportionate impact on a facility's TPS, while also continuing to further incentivize improvement on clinical measures through those individual measure weights. Consistent with our approach in the CY 2023 ESRD PPS final rule, we are proposing to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure

Domain so that each measure is weighted equally (87 FR 67251 through 67253). Since we are adding two new measures to the Reporting Measure Domain beginning with PY 2027, we would weight each measure within that domain equally at approximately 1.43, which is consistent with our previously finalized approach to weight each measure in the Reporting Measure Domain equally. We note that although we are proposing to change the number of measures in the Reporting Measure Domain and weights of certain individual measures in that domain, we are not proposing to change the weights of the five domains themselves, because we believe the proposed updates to individual measures and measure weights do not significantly impact the measure domains themselves such that updating the weights of the measure domains would be required to accommodate the updated individual measure weights. The previously finalized and newly proposed measures that would be included in each domain, along with the proposed new measure weights, beginning with PY 2027 are depicted in Table 22.

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TABLE 22: Proposed ESRD QIP Measure Domains and Weights Beginning with PY 2027

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure**	7.50
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Screening for Social Drivers of Health measure*	1.43
Screen Positive Rate for Social Drivers of Health reporting measure****	1.43
Facility Commitment to Health Equity reporting measure****	1.43
Hypercalcemia reporting measure	1.43
MedRec reporting measure	1.43
NHSN Dialysis Event reporting measure	1.43
COVID-19 HCP Vaccination reporting measure	1.43

*We are proposing to add the Screening for Social Drivers of Health measure beginning with PY 2027, as discussed in section IV.D.2 of this proposed rule.

**We are proposing to update the Clinical Depression Screening and Follow-Up measure beginning with PY 2026, as discussed in section IV.C.4 of this proposed rule.

***We are proposing to add the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.D.3 of this proposed rule.

****We are proposing to add the Facility Commitment to Health Equity reporting measure beginning with PY 2026, as discussed in section IV.C.2 of this proposed rule.

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We welcome public comment on these proposals.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home

dialysis and kidney transplantation, support Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are

associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.³⁰³ CMS excludes all U.S. Territories from the Selected Geographic Areas.

³⁰³ ZIP code™ is a trademark of the United States Postal Service.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDP), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDP applies to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we would make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022 and ending June 30, 2027.

In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We made adjustments to the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive Living Donor Transplant (LDT) Beneficiaries (86 FR 61950 through 61951). We modified the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through

61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth Measurement Year (MY) of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers (87 FR 67278 through 67280), and finalized our intent to publish participant-level model performance information to the public (87 FR 67280).

B. Summary of the Proposed Provisions to the ETC Model

In the Specialty Care Models final rule (85 FR 61114), we established our policies for targeted reviews of the calculation of an ETC Participant's Modality Performance Score (MPS). As described in § 512.390(c), targeted reviews are limited to the calculation of the MPS and may not pertain to the methodologies used to calculate the MPS, home dialysis rate, transplant rates, achievement and improvement benchmarks, or the PPA amounts. ETC Participants have 90 days following the availability of the MPS to submit a targeted review request. CMS responds to each targeted review request that is received within the 90-day time period. CMS may solicit additional information from the ETC Participant in support of the request after which a determination is made as to whether there was an error in the calculation of the ETC Participant's MPS that results in an incorrect PPA being applied during the PPA period. In such a scenario, CMS notifies the ETC Participant and resolves any resulting discrepancy in payment that arises from the application of an incorrect PPA.

We are proposing revisions to our regulations at § 512.390 to clarify the ability of the CMS Administrator to review targeted review determinations. In particular, we are proposing to add § 512.390(d) to specify that the CMS Administrator may review targeted review requests when administrative review is requested by ETC Participants within 15-calendar days of a targeted review request determination made by CMS.

We are proposing that within 45 days of the date of the ETC Participant's request for administrative review, the

CMS Administrator may act as follows: (i) decline to review the targeted review request determination made by CMS, (ii) render a final decision based on the CMS Administrator's review of the targeted review request determination, or (iii) choose to take no action on the request for administrative review. We are proposing that targeted review request determinations made by the CMS Administrator are considered final if the CMS Administrator declines an ETC Participant's request for administrative review or if the CMS Administrator does not take any action on the ETC Participant's request for administrative review by the end of the 45-day period described.

We are also proposing a conforming change to delete the existing provision in § 512.390(c)(5), which states that decisions based on targeted review are final, and there is no further review or appeal.

These proposed changes would ensure that accountability for the decisions of CMS is vested in a principal officer and would bring the targeted review process to a more similar posture as other CMS appeals entities that provide for CMS Administrator review. These proposed revisions would also ensure that ETC Participants are aware that administrative review is available to ETC Participants who wish to seek additional review of the results of a targeted review request.

We seek comment on this proposal.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 (ICRs).

A. ICRs Regarding the Proposed JW and JZ Reporting Requirements; Proposed Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS, Section II.B.1.h (OMB Control Number 0938–0997)

As discussed in section II.B.1.h of this proposed rule, we are proposing to require that beginning January 1, 2024, ESRD facilities must report information on claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data). Additionally, we are proposing to require ESRD facilities to report the JZ modifier for all such drugs and biological products with no discarded amounts beginning no later than January 1, 2024. Based on our analysis of ESRD PPS claims as well as the billing guidance in sections 8 and 17 of the Medicare Claims Processing Manual, we have determined that the proposed JW modifier requirement reflects current practices for ESRD facilities, and would not significantly increase burden for ESRD facilities. Additionally, the proposed JZ modifier requirement is not expected to increase burden on ESRD facilities because under the guidance provided regarding use of the JW modifier, the ESRD facility should already have processes in place in order to determine, in the case of certain drugs and biological products, whether or not there are any discarded units from a single use container or package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form. Additionally, as discussed in section II.B.1.h of this proposed rule, any separately payable drugs or biological products that ESRD facilities bill for using the AY modifier would already be subject to the JW and JZ modifier policies under Medicare Part B. Therefore, most ESRD facilities should already be set up to report the JW and JZ modifiers in such circumstances, and would reasonably be able to report these modifiers for renal dialysis drugs and biological products as well.

B. ICRs Regarding the Proposal to Require Time on Machine Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis; Section II.B.1.j (OMB Control Numbers 0938–0997)

We are proposing to require ESRD facilities to submit data and information on ESRD PPS claims regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use involved (that is, reporting on ESRD PPS patient claims the minutes of time on machine for each hemodialysis treatment) in furnishing renal dialysis services at ESRD facilities. We have developed monetary estimates of the amount of ESRD facility staff time required to report this information on claims in order to estimate the costs associated with the proposal to require the reporting of time on machine data. We have included those estimates in the Regulatory Impact Analysis section of this proposed rule. We acknowledge the burden associated with this proposed requirement, but we note that the burden associated with the CMS–1450 institutional claim form already accounts for the variability in the number and type of codes submitted for each claim.

C. Additional Information Collection Requirements

1. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the CDC's National Healthcare Safety Network (NHSN), as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available median hourly wage of a Medical Records Specialist is \$22.43 per hour.³⁰⁴ We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to

reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimated an hourly labor cost of \$44.86 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this updated wage estimate, along with updated facility and patient counts, to update our estimate for the total information collection burden in the ESRD QIP for PY 2026 that we discussed in the CY 2023 ESRD PPS final rule (87 FR 67281) and to estimate the total information collection burden in the ESRD QIP for PY 2027, which we discuss further in section VIII.C.3 of this proposed rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2026 and PY 2027 (OMB Control Numbers 0938–1289 and 0938–1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the EQRS (formerly, CROWNWeb) data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate EQRS data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In this proposed rule, we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement (84 FR 60787). If 300 facilities are requested to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records Specialists or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would

³⁰⁴ <https://www.bls.gov/oes/current/oes292072.htm>. Accessed on January 3, 2023.

be approximately \$33,645 (750 hours × \$44.86), or an annual total of approximately \$112.15 (\$33,645/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289; Expiration date: November 30, 2025).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. Applying this policy for NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are requested to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records Specialists or similar staff would submit these data, using the newly available wage estimate of a Medical Records Specialist, we estimate that the aggregate cost of the NHSN data validation each year would be approximately \$67,290 (1,500 hours × \$44.86), or a total of approximately \$224.30 (\$67,290/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1340; Expiration date: November 30, 2025).

3. Estimated EQRS Reporting Requirements for PY 2026 and PY 2027 (OMB Control Number 0938–1289)

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the

number of facilities submitting data to EQRS. In the CY 2023 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2026 ESRD QIP was approximately \$220 million for approximately 4,908,291 total burden hours (87 FR 67282).

We are proposing several changes to the ESRD QIP measure set in this proposed rule that would affect the burden associated with EQRS reporting requirements for PY 2026 or PY 2027. Beginning with PY 2026, we are proposing to remove two measures from the ESRD QIP measure set and to add one measure to the ESRD QIP measure set. For PY 2027 and for subsequent years, we are proposing to add two measures to the ESRD QIP measure set. We have re-calculated the burden estimate for PY 2026 to reflect the impact of these proposals if finalized, using updated estimates of the total number of ESRD facilities, the total number of patients nationally, and wages for Medical Records Specialists or similar staff, as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. In this proposed rule, we estimate that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. We are further updating these estimates in this proposed rule. There are 126 data elements proposed for 514,406 patients across 7,847 facilities, for a total of 64,815,156 elements (126 data elements × 514,406 patients). At 2.5 minutes per element, this would yield approximately 344 hours per facility. Therefore, the PY 2026 burden would be 2,700,632 hours (344 hours × 7,847 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2026 total burden cost is approximately \$121.1 million (2,700,632 hours × \$44.86).

There would also be an incremental burden change from PY 2026 to PY 2027 because we are proposing to add two new measures beginning with PY 2027. For PY 2027, there are 136 data elements proposed for 514,406 patients across 7,847 facilities. At 2.5 minutes per element, this would yield approximately 371 hours per facility. Therefore, the PY 2027 burden would be 2,914,967 hours (371 hours × 7,847 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2027 total burden cost would be approximately \$130.7 million (2,914,967 hours × \$44.86).

If you comment on these information collection requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by August 25, 2023.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This proposed rule proposes updates and policy changes to the CY 2024 ESRD wage index values, the proposed combined wage index and TPEAPA budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2024 for renal dialysis services furnished to ESRD beneficiaries.

This rule also has a number of proposed policy changes to improve payment stability and adequacy under the ESRD PPS. These include a proposed transitional add-on payment adjustment for pediatric patients and a proposed add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD

PPS functional categories after the end of the TDAPA. We are also proposing updates to the administrative process for the LVPA, requiring ESRD facilities to report on claims billing units of any discarded amounts of certain drugs and biological products, and requiring ESRD facilities to report “time on machine” data on ESRD PPS claims for all in-center hemodialysis treatments. We believe that each of these changes would improve payment stability and adequacy under the ESRD PPS.

2. AKI

This proposed rule proposes updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B of this proposed rule, we are also proposing to apply to all AKI dialysis payments the updates to the ESRD PPS base rate and wage index. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2024 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS by up to two percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This proposed rule proposes updates for the ESRD QIP, including removing the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning with PY 2026, removing the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026, updating the COVID-19 Vaccination Coverage Among HCP beginning with PY 2026, converting the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure beginning with PY 2026, and adding the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. This proposed rule also proposes to add the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027.

4. ETC Model

We believe it is necessary to propose certain changes to the ETC Model to acknowledge the availability of administrative review of targeted review requests. This proposed revision is necessary to provide transparency to

ETC Participants regarding the avenue available to them should they wish to seek additional review of the results of a targeted review request determination.

B. Overall Impact

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 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section

3(f)(1) of Executive Order 12866 (\$200 million or more in any 1 year). Based on our estimates of the combined impact of the ESRD PPS, ESRD QIP, and ETC provisions in this proposed rule, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) economic effect. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this proposed rule, and the Department have provided the following assessment of its impact. We solicit comments on the regulatory impact analysis provided.

C. Impact Analysis

1. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately \$130 million in Medicare payments to ESRD facilities in CY 2024, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, the budget-neutral transitional pediatric ESRD add-on payment adjustment, the beginning of the proposed post-TDAPA add-on payment adjustment, and continuation of the approved TDAPA from CY 2023 until March 31, 2024.

2. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately \$1 million in Medicare payments to ESRD facilities in CY 2024.

3. ESRD QIP

We estimate that the proposed updates to the ESRD QIP will result in \$20 million in estimated payment reductions across all facilities for PY 2026.

4. ETC Model

We estimate that the proposed changes to the ETC Model would not impact the Model’s projected direct savings from payment adjustments alone. As described in the CY 2023 ESRD PPS final rule, we estimate that the Model would generate \$28 million in direct savings related to payment adjustments over 6.5 years (87 FR 67297 through 67299).

5. Summary of Impacts

We estimate that the combined impact of the proposals in this rule on payments for CY 2024 is \$131 million based on the estimates of the updates to the ESRD PPS and the AKI payment rates. We estimate an additional \$4 million in costs associated with the

proposed policy to require ESRD facilities to report time on machine data. We estimate the impacts of the ESRD QIP for PY 2026 to be \$121.1 million in information collection burden and \$20 million in estimated payment reductions across all facilities. Additionally, we estimate the impacts of the ESRD QIP for PY 2027 to be \$130.7 million in information collection burden and \$17.3 million in estimated payment reductions across all facilities. Finally, we estimate that the proposed changes to the ETC model in this proposed rule would not impact the Model's projected direct savings from payment adjustments alone.

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the CY 2024 ESRD PPS and AKI payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities would enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished at ESRD facilities by 1.7 percent based on the proposed CY 2024 ESRD PPS market basket percentage increase less the proposed CY 2024 productivity adjustment would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that the overall payment rate for the ESRD PPS would increase by 1.6 percent.

2. Costs

a. ESRD PPS and AKI

As discussed in section II.B.1.j of this proposed rule, we are proposing to require ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use would be used to apportion composite rate costs for use in the case-mix adjustment under the ESRD PPS. We estimate that there would be an increase in costs for ESRD facilities associated with this

proposed reporting requirement; however, as we previously noted in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), we are aware that many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every dialysis treatment, minimizing the additional burden of reporting this metric on claims. For those ESRD facilities that use EHRs, we estimate that there would be only very minimal additional staff time required to report such time on machine data on ESRD PPS claims for renal dialysis services. For those ESRD facilities that do not use EHRs, we estimate that additional staff time would be required to take note of the time at which hemodialysis began and the time at which hemodialysis ended, and subtract the start time from the end time to determine the total number of minutes of hemodialysis. Conservatively, we estimate this would require no more than 1 minute per treatment.

To calculate the annual additional ESRD facility staff time that would be associated with reporting time on machine data on ESRD PPS claims for renal dialysis services, we multiply the estimated time per treatment by the number of dialysis treatments. Based on the most recent available CY 2022 ESRD PPS claims for this proposed rule, we estimate there were approximately 29.8 million treatments. However, as discussed in section II.B.1.j, we are proposing to limit this reporting requirement to in-center claims. We estimate that approximately 14.6 percent of claims are for home dialysis, and therefore we reduce our estimate of the total number of treatments by 14.6 percent. Additionally, we believe it is reasonable to assume that LDOs would utilize existing systems and processes to document treatment duration in the EHR and send that information to the claim. Based on the latest available data as shown in Table 23, approximately 77.9 percent of treatments were furnished by LDOs. Therefore, we estimate that the additional costs associated with this proposed time on machine reporting requirement would be associated with approximately 5.6 million in-center, non-LDO dialysis treatments per year.

Additionally, ESRD facilities already report time on machine data on a monthly basis in the EQRS for a single dialysis session. This means that for a patient who receives 156 dialysis treatments per year, the duration of twelve of those sessions would already be reported in the EQRS. We do not believe there would be any additional staff time required to report time on

machine data on ESRD PPS claims for the treatments already reported in EQRS. Therefore, we estimate that the additional staff time would be needed for reporting time on machine for 144 out of 156 treatments per year for the typical patient. For our cost estimate, we multiplied our estimate of 5.6 million in-center dialysis treatments by a factor of (144/156), which equals approximately 5.2 million treatments per year.

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates. We believe it is reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals reporting time on machine data. As discussed in the CY 2016 ESRD PPS final rule (80 FR 69069), this is consistent with our assumptions about the types of employees tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available median hourly wage of a Medical Records and Health Information Technician is \$23.67 per hour.³⁰⁵ We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We note that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimate an hourly labor cost of \$47.34 as the basis of the wage estimates for the estimate of cost associated with the proposed requirement to report time on machine data on ESRD PPS claims for renal dialysis services.

Based on the figures discussed in the preceding paragraphs, we estimate that total additional staff time each year for ESRD facilities associated with the proposed requirement to report time on machine data is equal to 5.2 million × 1 minute = 5.2 million minutes = 86,667 hours. We estimate the total annual cost associated with this proposed

³⁰⁵ <https://www.bls.gov/oes/current/oes292099.htm>.

requirement is equal to 86,667 hours $\times$ \$47.34 = \$4,102,815.78 per year.

We recognize that some non-LDO ESRD facilities may also choose to adopt an automated process, rather than a manual process. Therefore, the estimate of \$4,102,815.78, calculated based on 5.2 million treatments, represents the upper limit of our burden estimate. For ESRD facilities that choose to utilize existing systems and processes to document treatment duration in the EHR and send that data to the claim, we estimate the burden associated with our proposed requirement to report time on machine data would be minimal.

b. ESRD QIP

For PY 2026 and PY 2027, we have updated the estimated costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of ESRD facilities, the total number of patients nationally, wages for Medical Records Specialists or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study) or the NHSN validation study. We have updated our methodology for calculating the annual burden associated with the information collection requirements for EQRS reporting based on our proposed measure updates for PY 2026 and PY 2027.

We also updated the payment reduction estimates based on our proposals in this proposed rule, using more recent data for the measures in the ESRD QIP measure set. We estimate that as a result of our proposed and previously finalized policies for PY 2026, there would be approximately \$121.1 million in information collection burden and an additional \$20 million in estimated payment reductions across all facilities, for a total estimated impact of \$141.1 million.

For PY 2027, we estimate that as a result of our proposed and previously finalized policies for PY 2027, there would be approximately \$130.7 million

in information collection burden and \$17.3 million in estimated payment reductions across all facilities, for a total estimated impact of \$148 million.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rate would result in a total increase of approximately \$130 million in Medicare payments to ESRD facilities in CY 2024, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately \$1 million in Medicare payments to ESRD facilities in CY 2024 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary co-insurance payments. We estimate approximately \$100 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately \$30 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the proposed rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections

of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this proposed rule is \$115.22 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 206 minutes (3.43 hours) for the staff to review half of this proposed rule, which has a total of approximately 103,000 words. For each entity that reviews the rule, the estimated cost is \$395.20 (3.43 hours $\times$ \$115.22). Therefore, we estimate that the total cost of reviewing this regulation is \$115,003.20 (\$395.20 $\times$ 291).

5. Impact Statement and Table

a. CY 2024 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2023 to estimated payments in CY 2024. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2023 and CY 2024 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we are able to calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we used CY 2022 data from the Medicare Part A and Part B Common Working Files as of 2/17/2023, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2022 claims to 2023 and 2024 using various updates. The updates to the ESRD PPS base rate are described in section II.B.1.d of this proposed rule. Table 23 shows the impact of the estimated CY 2024 ESRD PPS payments compared to estimated Medicare payments to ESRD facilities in CY 2023.

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TABLE 23: Impacts of the Proposed Changes in Medicare Payments to ESRD Facilities for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments ^{1,2} (E)	Wage Index Changes (F)	Total Percent Change ³ (G)
All Facilities	7,833	29.8	-0.1%	0.0%	0.0%	0.0%	1.6%
Type							
Freestanding	7,481	28.6	-0.1%	0.0%	0.0%	0.0%	1.6%
Hospital based	352	1.1	-0.2%	0.8%	0.0%	0.2%	2.6%
Ownership Type							
Large dialysis organization	6,068	23.2	-0.1%	0.0%	0.0%	0.0%	1.6%
Regional chain	901	3.6	-0.1%	0.0%	-0.1%	-0.1%	1.4%
Independent	451	1.7	-0.1%	0.0%	0.0%	0.6%	2.2%
Hospital based	352	1.1	-0.2%	0.8%	0.0%	0.2%	2.6%
Unknown	61	0.0	0.0%	0.0%	0.0%	0.2%	1.8%
Geographic Location							
Rural	1,264	4.2	-0.1%	0.0%	0.0%	-0.5%	1.1%
Urban	6,569	25.6	-0.1%	0.0%	0.0%	0.1%	1.7%
Census Region							
East North Central	1,223	4.0	-0.1%	0.0%	0.0%	-0.4%	1.2%
East South Central	616	2.0	-0.1%	0.0%	0.0%	-0.4%	1.2%
Middle Atlantic	893	3.7	-0.1%	0.0%	0.0%	0.8%	2.4%
Mountain	438	1.6	-0.1%	0.0%	0.0%	-0.5%	1.1%
New England	200	1.0	-0.1%	0.0%	0.0%	-0.5%	1.1%
Pacific ⁴	977	5.1	-0.1%	0.0%	0.0%	0.0%	1.6%
Puerto Rico and Virgin Islands	52	0.1	0.0%	0.0%	0.0%	0.0%	1.7%
South Atlantic	1,820	6.5	-0.1%	0.0%	0.0%	0.2%	1.8%
West North Central	495	1.7	-0.1%	0.0%	0.0%	-0.4%	1.2%
West South Central	1,119	4.0	-0.1%	0.1%	0.0%	-0.1%	1.6%

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	TPEAPA (D)	Changes to TDAPA and Post-TDAPA Payments ^{1,2} (E)	Wage Index Changes (F)	Total Percent Change ³ (G)
Facility Size							
Less than 4,000 treatments	1,267	1.5	-0.1%	0.3%	0.0%	-0.1%	1.9%
4,000 to 9,999 treatments	3,294	9.2	-0.1%	0.0%	0.0%	-0.1%	1.5%
10,000 or more treatments	3,272	19.0	-0.1%	0.0%	0.0%	0.0%	1.6%
Unknown	0	0.0	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of Pediatric Patients							
Less than 2%	7,732	29.6	-0.1%	0.0%	0.0%	0.0%	1.6%
Between 2% and 19%	37	0.2	-0.1%	1.5%	0.0%	-0.7%	2.5%
Between 20% and 49%	9	0.0	0.0%	8.6%	0.0%	-1.1%	9.3%
More than 50%	55	0.0	0.1%	25.2%	0.0%	0.0%	27.6%

¹ This column includes the impact of the end of TDAPA payment for KORSUVATM and the start of the proposed post-TDAPA payment adjustment beginning in April, 2024. This proposed change is not budget neutral, but we estimate the overall change in total payments would be a decrease of less than 0.1 percent.

² CY 2023 TDAPA for KORSUVATM will continue through March 31, 2024, under the ESRD PPS. We estimate approximately \$1.7 million in TDAPA spending, of which, approximately \$345,000 would be attributed to beneficiary coinsurance amounts.

³ This column includes the impact of the proposed updates in columns (C) through (F) in Table 23, and of the proposed ESRDB market basket percentage increase for CY 2024 of 2.0 percent, reduced by 0.3 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

⁴ Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.1.c of this proposed rule is shown in column C. For CY 2024, the impact on all ESRD facilities as a result of the proposed changes to the outlier payment policy would be a 0.1 percent decrease in estimated Medicare payments.

Column D shows the effect of the proposed TPEAPA as described in section II.B.1.g of this proposed rule. This adjustment would be implemented in a budget neutral manner, so the total impact of this change would be 0.0 percent. However, there would be distributional impacts of this proposed

change, primarily a 25.2 percent increase to payments to Pediatric ESRD facilities (with more than 50 percent of patients under age 18). This proposed policy change also corresponds to a 0.8 percent increase to hospital-based ESRD facilities. Because the budget neutrality factor for this proposed policy is so small, the impact analysis found no significant decrease to any ESRD facility as the total decrease in payments for ESRD facilities that predominantly serve adults would still be less than 0.05 percent.

Column E shows the effect of year-over-year payment changes related to the proposed post-TDAPA add-on payment adjustment as described in section II.B.1.i of this proposed rule and current TDAPA payments. The post-TDAPA add-on payment adjustment would not be budget neutral; however,

we estimate the difference between total payments in CY 2023 during which time payment is made using the TDAPA under the ESRD PPS, and estimated total payments in CY 2024 under the proposed post-TDAPA add-on payment adjustment would be less than 0.1 percent. Therefore, the total impact of this change as compared to current TDAPA payments is 0.0 percent.

Column F reflects the effect of the proposed update to the ESRD PPS wage index as described in section II.B.1.c of this proposed rule. This update would be budget neutral, so the total impact of this policy change is 0.0 percent. However, there would be distributional impacts of this change. The largest increase would be to mid-Atlantic ESRD facilities that would receive 0.8 percent higher payments as a result of the proposed updated ESRD PPS wage

index. The largest decrease would be to ESRD facilities with more than 20 percent and less than 50 percent pediatric patients, who would receive 1.1 percent lower payments as a result of the proposed updated ESRD PPS wage index.

Column G reflects the overall impact, that is, the effects of the proposed outlier policy changes, the TPEAPA, the post-TDAPA payment adjustment, the updated wage index, and the payment rate update as proposed in section II.B.1.d of this proposed rule. The proposed ESRD PPS payment rate update for CY 2024 is 1.7 percent, which reflects the proposed ESRDB market basket percentage increase for CY 2024 of 2.0 percent and the proposed productivity adjustment of 0.3 percent. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated Medicare payments in CY 2024. The categories of types of ESRD facilities in the impact table show impacts ranging from a 1.1 percent increase to a 27.6 percent increase in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2024, we estimate that the ESRD PPS would have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2024 would be approximately \$6.4 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 4.2 percent in CY 2024.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.6 percent overall increase in the CY 2024 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2024, which translates to approximately \$30 million.

(5) Alternatives Considered

(i) Transitional Pediatric ESRD Add-On Payment Adjustment

As discussed in section II.B.1.g.(4) of this proposed rule, we are proposing to implement a transitional add-on payment adjustment of 30 percent for Pediatric ESRD Patients, which we would call the TPEAPA. We also considered, but did not propose, an alternative payment structure which would phase in the adjustment over 3 years starting at 10 percent for the first year and 20 percent for the second year.

(ii) Proposed Add-On Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends

As discussed in section II.B.1.i.(3) of this proposed rule, we are proposing an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. We also considered, but did not propose, an alternative methodology for calculating this payment adjustment which would incorporate a reconciliation of all the formerly separately billable drugs against the calculated post-TDAPA payment adjustment. Additionally, we considered but did not propose alternative approaches to applying and calculating this add-on payment adjustment for specific patient populations.

(iii) Proposal To Require Reporting Time on Machine Data on ESRD PPS Claims for Renal Dialysis Services

As discussed in section II.B.1.j.(5) of this proposed rule, we are proposing to require ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. This patient-level reporting on resource use would be used to apportion composite rate costs for use in the case-mix adjustment. We also considered, but did not propose, to use dialysis duration data from EQRS to apportion composite rate costs for this purpose. We discuss why we did not propose this alternative in further detail in section II.B.1.j.(5) of this proposed rule.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2024

(1) KORSUVA™ (difelikefalin)

One renal dialysis drug for which the TDAPA was paid in CY 2022 and CY 2023 would continue to be eligible for the TDAPA in CY 2024. CMS Transmittal 11295,³⁰⁶ implemented the 2-year TDAPA period specified in § 413.234(c)(1) for KORSUVA™ (difelikefalin). The TDAPA payment period began on April 1, 2022 and will continue through March 31, 2024. As set forth in § 413.234(c), TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based the CY 2024 impacts on the most current 72x claims data from May 2022, when utilization first appeared on the claims, through February 2023. During that timeframe, the average monthly TDAPA payment amount for KORSUVA™ was \$575,000. In applying that average to the 3 remaining months of the TDAPA payment period in CY 2024, we estimate \$1,725,000 in spending (\$575,000 * 3 = \$1,725,000) of which, approximately \$345,000 (\$1,725,000 * 0.20 = \$345,000) would be attributed to beneficiary coinsurance amounts.

c. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the proposed changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2023 to estimated Medicare payments in CY 2024. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2023 and CY 2024 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we are able to calculate both current Medicare payments and new Medicare payments.

³⁰⁶ CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022 and is available at: <https://www.cms.gov/files/document/r11295CP.pdf>.

For this proposed rule, we used CY 2022 data from the Medicare Part A and Part B Common Working Files as of 2/17/2023, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the	2022 claims to 2023 and 2024 using various updates. The proposed updates to the AKI payment amount are described in section III.B of this proposed rule. Table 24 shows the impact of the estimated CY 2024	Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2023.

TABLE 24: Impacts of the Proposed Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2024

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change ¹ (D)
All Facilities	5,048	268.1	-0.1%	1.6%
Type				
Freestanding	4,934	262.9	-0.1%	1.6%
Hospital based	114	5.2	0.2%	1.8%
Ownership Type				
Large dialysis organization	4,159	220.3	-0.1%	1.5%
Regional chain	576	28.6	-0.1%	1.5%
Independent	174	13.3	0.6%	2.3%
Hospital based ²	114	5.2	0.2%	1.8%
Unknown	25	0.8	0.2%	1.8%
Geographic Location				
Rural	854	41.3	-0.5%	1.2%
Urban	4,194	226.8	0.0%	1.6%
Census Region				
East North Central	847	43.8	-0.4%	1.2%
East South Central	379	18.0	-0.3%	1.3%
Middle Atlantic	527	31.4	0.7%	2.4%
Mountain	298	19.3	-0.7%	0.9%
New England	145	6.5	-0.3%	1.3%
Pacific ³	617	41.3	-0.2%	1.5%
Puerto Rico and Virgin Islands	5	0.1	0.0%	1.7%
South Atlantic	1,215	63.9	0.1%	1.7%
West North Central	314	12.6	-0.3%	1.3%
West South Central	701	31.1	0.0%	1.7%
Facility Size				
Less than 4,000 treatments	565	22.2	0.0%	1.7%
4,000 to 9,999 treatments	2,160	102.9	-0.1%	1.5%
10,000 or more treatments	2,323	143.0	-0.1%	1.6%
Unknown	0	0.0	0.0%	0.0%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change ¹ (D)
Percentage of Pediatric Patients				
Less than 2%	5,036	267.6	-0.1%	1.6%
Between 2% and 19%	10	0.5	-2.0%	-0.4%
Between 20% and 49%	1	0.1	-1.6%	0.0%
More than 50%	1	0.0	-0.5%	1.2%

¹ This column includes the impact of the proposed updates in columns (C) as well as the impact of the proposed TPEAPA budget-neutrality adjustment factor in Table 24, and of the proposed ESRDB market basket percentage increase for CY 2024 (2.0 percent), reduced by 0.3 percentage point for the proposed productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

² Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

³ Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the CY 2024 wage indices.

Column D shows the overall impact, that is, the effects of proposed combined wage index and TPEAPA budget-neutrality adjustment factor, wage index updates, and the payment rate update of 1.7 percent, which reflects the proposed ESRDB market basket percentage increase for CY 2024 of 2.0 percent and the proposed productivity adjustment of 0.3 percentage point. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated Medicare payments in CY 2024. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of -0.4 percent to 2.4 percent in their CY 2024 estimated Medicare payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would

have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately \$70 million would be paid to ESRD facilities in CY 2024 as a result of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI

specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients, and as such, including those policies and adjustments is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

d. ESRD QIP

(1) Effects of the PY 2026 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS is described in our regulations at 42 CFR 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2026 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2026, as codified in our regulations at 42 CFR 413.177.

For the PY 2026 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 31.56 percent or 2,477 of the facilities

that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. Among an estimated 2,477 facilities that would receive a payment reduction, approximately 64 percent or 1,585 facilities would receive the smallest payment reduction of 0.5 percent. We are presenting an estimate

for the PY 2026 ESRD QIP to update the estimated impact that was provided in the CY 2023 ESRD PPS final rule (87 FR 67293 through 67296). Based on our proposed policies, the total estimated payment reductions for all the 2,477 facilities expected to receive a payment reduction in PY 2026 would be

approximately \$20,040,827. Facilities that do not receive a TPS do not receive a payment reduction.

Table 25 shows the overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

TABLE 25: Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5175	67.63%
0.5%	1585	20.71%
1.0%	673	8.80%
1.5%	176	2.30%
2.0%	43	0.56%

*195 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2026, we scored each facility on achievement and improvement on several clinical measures we have

previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table

19) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 26.

TABLE 26: Data Used to Estimate PY 2026 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021
Clinical Depression*	N/A	Jan 2021-Dec 2021

*Note: PPPW score and Clinical Depression score are based on achievement score only.

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included

in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the proposed policies outlined in section IV.C of this proposed rule. Facility reporting measure scores

were estimated using available data from CY 2021. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2026 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December

2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 27 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2026. The table also details the

distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the

performance period used for these calculations differs from the performance period we are using for the PY 2026 ESRD QIP, the actual impact of the PY 2026 ESRD QIP may vary significantly from the values provided here.

TABLE 27: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,847	35.0	7,652	2,477	-0.23%
Facility Type:					
Freestanding	7,471	33.7	7,315	2,336	-0.23%
Hospital-based	376	1.4	337	141	-0.33%
Ownership Type:					
Large Dialysis	5,964	27.1	5,881	1,679	-0.19%
Regional Chain	904	4.3	893	364	-0.31%
Independent	466	2.1	451	252	-0.50%
Hospital-based (non-chain)	376	1.4	337	141	-0.33%
Unknown	137	0.1	90	41	-0.63%
Facility Size:					
Large Entities	6,868	31.4	6,774	2,043	-0.20%
Small Entities ¹	842	3.5	788	393	-0.43%
Unknown	137	0.1	90	41	-0.63%
Rural Status:					
1) Yes	1,281	5.0	1,244	326	-0.17%
2) No	6,566	30.0	6,408	2,151	-0.24%
Census Region:					
Northeast	1,087	5.5	1,059	372	-0.26%
Midwest	1,736	6.6	1,681	552	-0.24%
South	3,570	15.2	3,482	1,205	-0.25%
West	1,393	7.4	1,370	307	-0.15%
US Territories ²	61	0.3	60	41	-0.45%
Census Division:					
Unknown	9	0.1	9	5	-0.27%
East North Central	1,222	4.7	1,198	438	-0.27%
East South Central	618	2.4	602	188	-0.21%
Middle Atlantic	886	4.3	860	317	-0.27%
Mountain	436	1.9	428	100	-0.15%
New England	201	1.2	199	55	-0.20%
Pacific	957	5.5	942	207	-0.15%
South Atlantic	1,827	8.0	1,778	652	-0.26%
West North Central	514	1.9	483	114	-0.16%
West South Central	1,125	4.8	1,102	365	-0.25%
US Territories ²	52	0.1	51	36	-0.48%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,229	1.9	1,138	244	-0.18%
4,000-9,999 treatments	3,095	10.1	3,061	865	-0.20%
Over 10,000 treatments	3,358	22.9	3,355	1,321	-0.27%
Unknown	165	0.2	98	47	-0.67%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.

²Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(3) Effects of the PY 2027 ESRD QIP on ESRD Facilities

For the PY 2027 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately

29.29 percent or 2,299 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2027. Among an estimated 2,299 facilities that would receive a payment reduction, approximately 68.3 percent

or 1,571 facilities would receive the smallest payment reduction of 0.5 percent. The total payment reductions for all the 2,299 facilities expected to receive a payment reduction is approximately \$17,388,145. Facilities

that do not receive a TPS do not receive a payment reduction.

Table 28 shows the overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 28: Estimated Distribution of PY 2027 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5432	70.26%
0.5%	1571	20.32%
1.0%	606	7.84%
1.5%	118	1.53%
2.0%	4	0.05%

*Note: 116 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2027, we scored each facility on achievement and improvement on several clinical measures we have previously finalized

and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 26) in

accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 29.

TABLE 29: Data Used to Estimate PY 2027 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021
Clinical Depression*	N/A	Jan 2021-Dec 2021

*Note: PPPW score and Clinical Depression score are based on achievement score only

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR and SRR measures, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the proposed and

previously finalized policies outlined in section IV.D of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2021. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2027 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 30 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2027. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

TABLE 30: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,847	35.0	7,731	2,299	-0.20%
Facility Type:					
Freestanding	7,471	33.7	7,384	2,168	-0.20%
Hospital-based	376	1.4	347	131	-0.28%
Ownership Type:					
Large Dialysis	5,964	27.1	5,900	1,536	-0.16%
Regional Chain	904	4.3	893	354	-0.28%
Independent	466	2.1	460	237	-0.42%
Hospital-based (non-chain)	376	1.4	347	131	-0.28%
Unknown	137	0.1	131	41	-0.32%
Facility Size:					
Large Entities	6,868	31.4	6,793	1,890	-0.18%
Small Entities ¹	842	3.5	807	368	-0.36%
Unknown	137	0.1	131	41	-0.32%
Rural Status:					
1) Yes	1,281	5.0	1,255	313	-0.15%
2) No	6,566	30.0	6,476	1,986	-0.21%
Census Region:					
Northeast	1,087	5.5	1,076	329	-0.21%
Midwest	1,736	6.6	1,703	515	-0.20%
South	3,570	15.2	3,514	1,138	-0.22%
West	1,393	7.4	1,378	277	-0.13%
US Territories ²	61	0.3	60	40	-0.43%
Census Division:					
Unknown	9	0.1	9	5	-0.27%
East North Central	1,222	4.7	1,206	409	-0.23%
East South Central	618	2.4	607	179	-0.19%
Middle Atlantic	886	4.3	876	284	-0.22%
Mountain	436	1.9	431	97	-0.14%
New England	201	1.2	200	45	-0.16%
Pacific	957	5.5	947	180	-0.12%
South Atlantic	1,827	8.0	1,799	617	-0.23%
West North Central	514	1.9	497	106	-0.13%
West South Central	1,125	4.8	1,108	342	-0.22%
US Territories ²	52	0.1	51	35	-0.46%
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,229	1.9	1,173	233	-0.15%
4,000-9,999 treatments	3,095	10.1	3,061	839	-0.18%
Over 10,000 treatments	3,358	22.9	3,355	1,180	-0.23%
Unknown	165	0.2	142	47	-0.34%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.

²Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(4) Effects on Other Providers

The ESRD QIP is applicable to ESRD facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as facilities work to reduce the number of

unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(5) Effects on the Medicare Program

For PY 2027, we estimate that the ESRD QIP would contribute approximately \$17,388,145.07 in Medicare savings. For comparison, Table 31 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2027.

TABLE 31: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2027

Payment Year	Estimated Payment Reductions
PY 2027	\$17,388,145
PY 2026	\$20,040,827
PY 2025	\$32,457,693 (87 FR 67297)
PY 2024	\$17,104,031 (86 FR 62011)
PY 2023	\$5,548,653 (87 FR 67297)
PY 2022	\$0 ³⁰⁷ (86 FR 62011)
PY 2021	\$32,196,724 (83 FR 57062)
PY 2020	\$31,581,441 (81 FR 77960)
PY 2019	\$15,470,309 (80 FR 69074)
PY 2018	\$11,576,214 (79 FR 66257)

(6) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(7) Alternatives Considered

In section IV.C.5 of this proposed rule, we are proposing to remove the Ultrafiltration Rate reporting measure and the Standardized Fistula Rate

clinical measure, beginning with PY 2026. We considered not proposing to remove these measures. However, we concluded that proposing to remove these two measures was appropriate under our previously finalized measure removal factors. This approach would help to ensure that a facility's performance is assessed based on measures that continue to be meaningful parts of the ESRD QIP measure set.

e. ETC Model**(1) Overview**

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), and the CY 2023 ESRD PPS final rule (87 FR 67136) for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021, to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. We are proposing to revise our regulations at § 512.390 to acknowledge the ability of the CMS Administrator to review the results of ETC Participants' targeted review requests. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, please see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the ETC Model relative to baseline expenditures, where baseline

expenditures were defined as data from CYs 2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

Table 32 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year $t-1$ and year $t-2$ for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program would save a net total of \$43 million from the PPA and HDPA between January 1, 2021, and June 30, 2027 less \$15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be \$28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was also estimated to be \$28 million in savings (86 FR 62014 through 62016). Our proposal to make administrative review available to ETC Participants who wish to seek additional review of a targeted review determination is not expected to change this estimate.

(3) Medicare Estimate—Primary Specification, Assume Rolling Benchmark

³⁰⁷ In the CY 2022 ESRD PPS final rule, we adopted a special scoring methodology and payment policy for PY 2022 due to significant impacts related to the COVID-19 public health emergency (86 FR 61918 through 61919). Under this policy, we did not apply any payment reductions to ESRD facilities for PY 2022.

TABLE 32: Estimates of Medicare Program Savings (Rounded \$M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	6.5 Year Total*
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDP	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDP	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDP	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDP	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than \$1M each year, but are rounded up to \$1M to show what years they apply to. Similarly, the HD Training Costs are less than \$1M for years 2021-2024, but are rounded up to \$1M to indicate that costs were applied those years.

In Table 32, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The changes in this proposed rule would not impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes in this proposed rule will not impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2023 ESRD PPS final rule (87 FR 67136).

(6) Effects on Medicare Beneficiaries

Our proposal to provide the option for ETC Participants to seek administrative review of targeted review determinations will not impact the findings reported for the effects of ETC Model on Medicare beneficiaries in lieu of the ETC Model's likelihood of incentivizing ESRD facilities and Managing Clinicians to improve access to home dialysis and transplantation for Medicare beneficiaries. Further details on the impact of the ETC Model on

ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357), the CY 2022 ESRD PPS final rule (86 FR 61874), or the CY 2023 ESRD PPS final rule (87 FR 67136).

(7) Alternatives Considered

In this proposed rule, we are proposing to revise our regulations at 42 CFR 512.390 to acknowledge the availability of administrative review of targeted review requests. We considered retaining our current process, in which targeted review determinations are final with no further review or appeal; however, we believe that providing for administrative review of targeted review determinations is important to provide ETC Participants with transparency regarding the avenue that is available should they wish to seek review of their targeted review determination, to vest accountability for the decisions of CMS in a principal officer, and to bring the

ETC Model into alignment with CMS programs.

E. Accounting Statement

As required by OMB Circular A–4 (available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/

[circulars/A4/a-4.pdf](#)), we have prepared an accounting statement in Table 33 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 33: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2024)	
Category	Transfers
Annualized Monetized Transfers	\$100 million
From Whom to Whom	Federal Government to ESRD providers
Category	Transfers
Increased Beneficiary Co-insurance Payments	\$30 million
From Whom to Whom	Beneficiaries to ESRD providers
Category	Costs
Increased Reporting Burden for Time on Machine	\$4 million
For Whom	ESRD Facilities
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-\$20.0 million
From Whom to Whom	Federal Government to ESRD providers.
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	-\$17.3 million
From Whom to Whom	Federal Government to ESRD providers
ETC Model for July 1, 2022 through June 30, 2027	
Category	Transfers
Annualized Monetized Transfers	\$0.03 million
From Whom to Whom	Federal Government to ESRD facilities and Managing Clinicians

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F. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards, an ESRD facility is classified as a small business if it has total revenues of less than \$41.5 million in any 1 year. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than \$8.1 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 451 facilities that are independent and 352 facilities that are hospital-based, as shown in the ownership category in

Table 23, to be small businesses. These facilities represent approximately 10 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 806 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 364 nonprofit ESRD facilities that are also considered small businesses, there are 1,245 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

For the ESRD PPS updates in this proposed rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 2.6 percent increase in Medicare payments for CY 2024. An independent facility (as defined by ownership type) is likewise estimated to receive a 2.2 percent increase in Medicare payments for CY

2024. As shown in Table 23, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare payments by approximately 1.6 percent.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for \$70 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 2,477 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2026 ESRD QIP, 393 are ESRD small entity facilities. We present these findings in Table 25 (“Estimated Distribution of PY 2026 ESRD QIP Payment Reductions”) and Table 27 (“Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026”).

Regarding the ETC Model, in the Specialty Care Models final rule, we described our assumption, for the purposes of the regulatory impact analysis, that the great majority of Managing Clinicians are small entities by nature of meeting the SBA definition of a small business, but that the greater majority of ESRD facilities are not, as they are owned, either partially or entirely, by organizations that do not meet the SBA definition of a small entity. We described the low volume threshold exclusions and aggregation policies used in the ETC Model and our assessment that, in conjunction with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaries; the ETC Model will not have a significant impact on spending for a substantial number of small entities. For the purposes of this proposed rule, we have determined that our proposal to clarify the ability of the CMS Administrator to review targeted review determinations will not change the assessment that the ETC Model will not have a significant impact on spending for a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would have a significant impact on

operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 121 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 121 rural hospital-based ESRD facilities would experience an estimated 2.2 percent increase in payments. Therefore, the Secretary has certified that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Our proposal to clarify the ability of the CMS Administrator to review ETC Model targeted review determinations is not expected to change the Secretary’s assessment.

G. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately \$177 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$177 million in any 1 year. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal governments.

IX. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no

longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on the CMS website under the regulation number, CMS–1782–P, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices>. In addition to the Addenda, limited data set files (LDS) are available for purchase at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile>. Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: ESRDPayment@cms.hhs.gov.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 15, 2023.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Medicare, Penalties, 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 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.178 is amended by revising paragraphs (a)(8) and (c) to read as follows:

§ 413.178 ESRD quality incentive program.

(a) * * *

(8) *Minimum total performance score (mTPS)* means, with respect to a

payment year except payment year 2023, the total performance score that an ESRD facility would receive if it performed at the 50th percentile of national ESRD facility performance on all clinical measures during the baseline period, and it performed at the median of national ESRD facility performance on all reporting measures using data from the most recently available year before the performance period.

* * * * *

(c) *ESRD QIP measure selection, retention, and removal*—(1) *ESRD QIP measure selection*. CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include:

(i) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management;

(ii) Measures on dialysis adequacy;

(iii) To the extent feasible, a measure (or measures) of patient satisfaction;

(iv) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula);

(v) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based; and

(vi) Other measures that CMS specifies.

(2) *Use of endorsed measures*—(i) *General rule*. Measures specified by CMS under paragraph (c)(1) of this section will be endorsed by the entity with a contract under section 1890(a) of the Social Security Act, unless the exception in paragraph (c)(2)(ii) of this section applies.

(ii) *Exception*. CMS may specify a measure under paragraph (c)(1) of this section that does not meet the requirement in paragraph (c)(2)(i) of this section if:

(A) CMS has determined that a specified area or medical topic is appropriate for inclusion in the ESRD QIP;

(B) CMS has not identified a feasible and practical measure with respect to that specified area or medical topic that has been endorsed by the entity with a contract under section 1890(a) of the Social Security Act; and

(C) CMS has given due consideration to measures that have been endorsed or adopted by a consensus organization.

(3) *Updating of measure specifications*. CMS uses rulemaking to make substantive updates to the specifications of measures used in the

ESRD QIP. CMS announces technical measure specification updates through the QualityNet website (<https://qualitynet.cms.gov>) and listserv announcements.

(4) *Measure retention*. All measures specified for the ESRD QIP measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(5) *Measure removal factors*—(i) *General rule*. CMS may remove or replace a measure based on one or more of the following factors:

(A) *Factor 1*. Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.

(B) *Factor 2*. Performance or improvement on a measure does not result in better or the intended patient outcomes.

(C) *Factor 3*. A measure no longer aligns with current clinical guidelines or practice.

(D) *Factor 4*. A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.

(E) *Factor 5*. A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.

(F) *Factor 6*. Collection or public reporting of a measure leads to negative or unintended consequences.

(G) *Factor 7*. It is not feasible to implement the measure specifications.

(H) *Factor 8*. The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception*. CMS may retain a measure that meets one or more of the measure removal factors described in paragraph (c)(5)(i) of this section for reasons including, but not limited to, that the measure addresses a gap in quality that is so significant that removing the measure would lower the quality of care furnished by facilities, or that the measure is statutorily required.

(iii) *Patient safety exception*. Upon a determination by CMS that the continued requirement for facilities to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the ESRD QIP measure set. CMS will, upon removal of the measure—

(A) Provide notice to facilities and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if facilities continued to submit data on the measure; and

(B) Provide notice of the removal in the **Federal Register**.

* * * * *

■ 3. Section 413.198 is amended by revising paragraphs (a) and (b)(3)(iii) and adding paragraphs (b)(5) and (6) to read as follows:

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope*. This section implements sections 1881(b)(2)(B)(i) and 1881(b)(14) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) * * *

(3) * * *

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

* * * * *

(5) Each ESRD facility must submit data and information of the types and in the formats established by CMS for the purpose of estimating patient-level and facility-level variation in resource use involved in furnishing renal dialysis services. The data and information must include, but is not limited to:

(i) Beginning January 1, 2025, information reported on ESRD prospective payment system (PPS) claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility;

(ii) Information reported on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data); and

(iii) Information reported on ESRD PPS claims about any renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS for which there is no discarded amount, using the JZ modifier (or any successor modifier that includes the same data).

(6) Each ESRD facility must document in the beneficiary's medical record any discarded amounts of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

■ 4. Section 413.230 is amended by revising paragraphs (d) and (e) and adding paragraph (f) to read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(d) Any transitional drug add-on payment adjustment under § 413.234(c);

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d); and

(f) Any add-on payment adjustment for new renal dialysis drugs or biological products in existing ESRD PPS functional categories after the payment period for the transitional drug add-on payment adjustment has ended, as described in § 413.234(c)(3) and (g).

■ 5. Section 413.232 is amended by revising paragraphs (b)(1) and (2) and (g) introductory text and adding paragraphs (g)(5) and (6) to read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) * * *

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) of this section) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year, except as specified in paragraph (g)(6) of this section.

* * * * *

(g) To receive the low-volume adjustment, an ESRD facility must include in its attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraphs (g)(4) and (5) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

* * * * *

(5) For payment year 2024 and subsequent payment years, an ESRD facility may attest in the attestation specified in paragraph (e) of this section

that it would have met the requirements of paragraph (b)(1) of this section, except that for one or more of the most recent 3 cost reporting years the facility furnished 4,000 or more treatments because of temporary patient-shifting as a result of the closure or operational disruption of another ESRD facility due to a disaster or other emergency. For the purposes of the exception in this paragraph (g)(5), temporary patient-shifting is defined as providing renal dialysis services to one or more displaced patient(s) at any time through the end of the calendar year following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to one or more displaced patients. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(ii) The facility must request an exception under this paragraph (g)(5) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section for each cost reporting year that the facility furnishes treatments equal to or in excess of 4,000 due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(iii) Within 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency, or deny the request, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries for up to the first 4,000 dialysis treatments, on the basis of the exception in this paragraph (g)(5), during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 4,000 treatment threshold in a cost reporting year due to temporary patient-shifting as

a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met; and

(v) The facility must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that closed or experienced operational disruptions due to a disaster or other emergency and previously treated those patients, and must provide such supporting documentation to CMS and the MAC upon request.

(6) In the case of an ESRD facility that closes due to a disaster or other emergency and later reopens, the ESRD facility may attest in the attestation specified in paragraph (e) of this section that CMS has granted an exception to the requirements specified in paragraph (b)(2) of this section because it closed due to a disaster or other emergency. For any facility that so attests—

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) With 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and will inform both the facility and the MAC of its decision; and

(iii) If CMS approves the request, the exception under this paragraph (g)(6) will be applicable for a period consisting of the remainder of the cost reporting year (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) in which the closure occurred and the following full 2 cost reporting years. After this period the ESRD facility would follow the general attestation process for the low-volume adjustment specified in paragraphs (e) and (g) of this section.

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 days reopening and providing renal dialysis services. Within 30 days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all

other requirements for the low-volume adjustment are met.

(v) The ESRD facility must maintain documentation regarding its closure, and must provide such supporting documentation to CMS and/or the MAC upon request.

* * * * *

■ 6. Section 413.234 is amended by—

■ a. Adding paragraph (b)(1)(iii);

■ b. Revising paragraph (c)(1)(i); and

■ c. Adding paragraphs (c)(1)(ii), (c)(3), and (g).

The additions and revision read as follows:

§ 413.234 Drug designation process.

* * * * *

(b) * * *

(1) * * *

(iii) The new renal dialysis drug or biological product is paid for using the add-on payment adjustment described in paragraphs (c)(3) and (g) of this section, referred to as the post-transitional drug add-on payment adjustment (TDAPA) add-on payment adjustment.

* * * * *

(c) * * *

(1) * * *

(i) Following payment of the transitional drug add-on payment adjustment, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment as set forth in paragraphs (c)(3) and (g) of this section.

(ii) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

* * * * *

(3) For any new renal dialysis drug or biological product that is eligible for payment using the transitional drug add-on payment adjustment described in paragraphs (b)(1)(iii) and (c)(1) of this section, CMS applies a post-TDAPA add-on payment adjustment to all ESRD PPS claims that is calculated using the methodology set forth in paragraph (g) of this section. CMS will apply the post-TDAPA add-on payment adjustment beginning 8 calendar quarters after the first calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product, and ending 12 calendar quarters after the end of the last calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product. If CMS stops receiving the latest full calendar quarter of ASP data for the applicable renal dialysis drug or

biological product during the applicable time period specified in paragraph (c)(1) of this section or during the 3-year period following such applicable time period, CMS will not pay any post-TDAPA add-on payment adjustment for such product in any future year.

* * * * *

(g) *Post-TDAPA add-on payment adjustment methodology.* CMS uses the following methodology to calculate the post-TDAPA add-on payment adjustment described in paragraph (c)(3) of this section:

(1) CMS bases the calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. If the most recent full calendar quarter of ASP data reflects zero or negative sales, then the calculation is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment annually as the expenditure for the new renal dialysis drug or biological product divided by the total number of ESRD PPS treatments during the same period.

(3) CMS applies a reduction factor to the post-TDAPA add-on payment adjustment for case mix standardization to reflect estimated increases resulting from the application of the patient-level adjustments as described in paragraph (g)(5) of this section. This reduction factor is calculated based on the patient-level adjustments (as described in § 413.235) applicable to the most recent 12-month period of utilization of ESRD PPS claims.

(4) The amount of the post-TDAPA add-on payment adjustment is equal to 65 percent of the amount calculated in paragraph (g)(2) of this section, multiplied by the reduction factor specified in paragraph (g)(3) of this section, and multiplied by the market basket increase factor under § 413.220(a)(5).

(5) The post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under § 413.235.

■ 7. Section 413.235 is amended by revising paragraph (b) to read as follows:

§ 413.235 Patient-level adjustments.

* * * * *

(b) CMS adjusts the per treatment base rate for Pediatric ESRD Patients in accordance with section 1881(b)(14) (D)(iv)(I) of the Act as follows:

(1) To account for patient age and treatment modality; and

(2) Beginning January 1, 2024, to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under § 413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026.

* * * * *

■ 8. Section 413.236 is amended by revising paragraph (b)(2) to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

* * * * *

(b) * * *

(2) Is new, meaning a complete application has been submitted to CMS under paragraph (c) of this section within 3 years of the date of the Food and Drug Administration (FDA) marketing authorization;

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 9. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 10. Section 512.390 is amended by removing paragraph (c)(5) and adding paragraph (d) to read as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(d) *Review of targeted review decisions.* The Administrator may review a targeted review request when administrative review is requested by an ETC Participant within 15-calendar days of a targeted review request determination made by CMS.

(1) *Administrative review.* Within 45 days of the date of the ETC Participant's request for administrative review, the CMS Administrator may act as follows:

(i) Decline to review a targeted review request determination made by CMS;

(ii) Render a final decision based on the CMS Administrator's review of the targeted review request determination; or

(iii) Choose to take no action on the request for administrative review.

(2) *Administrative review determinations.* The targeted review determination made by the CMS Administrator is final if the CMS Administrator declines an ETC Participant’s request for administrative

review or if the CMS Administrator does not take any action on the ETC Participant’s request for administrative review by the end of the 45-day period described in paragraph (d)(1) of this section.

Dated: *June 23, 2023.*
Xavier Becerra,
Secretary, Department of Health and Human Services.
[FR Doc. 2023–13748 Filed 6–26–23; 4:15 pm]
BILLING CODE 4120–01–P



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Part III

Securities and Exchange Commission

17 CFR Part 240

Prohibition Against Fraud, Manipulation, or Deception in Connection With
Security-Based Swaps; Prohibition Against Undue Influence Over Chief
Compliance Officers; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–97656; File No. S7–32–10]

RIN 3235–AK77

Prohibition Against Fraud, Manipulation, or Deception in Connection With Security-Based Swaps; Prohibition Against Undue Influence Over Chief Compliance Officers

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (“SEC” or “Commission”) is adopting a final rule, under the Securities Exchange Act of 1934 (“Exchange Act”), that is designed to prevent fraud, manipulation, and deception in connection with effecting any transaction in, or attempting to effect any transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap. The rule takes into account the features fundamental to a security-based swap and the broad definitions of purchase and sale under the Exchange Act as they relate to security-based swaps. In addition, the Commission is adopting a final rule, under the Exchange Act, that makes it unlawful for any officer, director, supervised person, or employee of a security-based swap dealer (“SBSD”) or major security-based swap participant (“MSBSP”) (each SBSD and each MSBSP also referred to as an “SBS Entity” and together referred to as “SBS Entities”), or any person acting under such person’s direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the SBS Entity’s chief compliance officer (“CCO”) in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.

DATES: *Effective date:* August 29, 2023.

FOR FURTHER INFORMATION CONTACT: Pamela Carmody, Special Counsel, Rajal B. Patel, Senior Special Counsel, or Carol M. McGee, Associate Director, at (202) 551–5870, Office of Derivatives Policy, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8010.

SUPPLEMENTARY INFORMATION: First, the Commission is adopting 17 CFR 240.9j–1 (“Rule 9j–1”) under the Exchange Act, which is a new rule designed to prevent fraud, manipulation, and deception in

connection with effecting transactions in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap. The Commission is also adopting 17 CFR 240.15fh–4(c) (“Rule 15fh–4(c)”) under the Exchange Act, which is a new rule making it unlawful for any officer, director, supervised person, or employee of an SBS Entity, or any person acting under such person’s direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the SBS Entity’s CCO in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.

- I. Introduction
 - A. Background
 - B. Overview of Security-Based Swaps
 1. Security-Based Swaps Generally
 2. Security-Based Swap Market Developments
 - C. Overview of the Final Rules
 1. Rule 9j–1
 2. Rule 15fh–4(c)
- II. Rule 9j–1: Prohibition Against Fraud, Manipulation, and Deception in Connection With Security-Based Swaps
 - A. Misconduct “In Connection With” “Purchases,” “Sales,” or “Effecting Transactions”
 1. Proposed Approach
 2. Commission Action
 - a. In Connection With Purchases or Sales
 - b. Effecting Transactions
 - B. Fraudulent, Manipulative, or Deceptive Conduct
 1. Proposed Approach
 2. Commission Action
 - a. Scienter and Negligence Standards
 - b. Attempted Conduct
 - C. Prohibition on Price Manipulation
 1. Proposed Approach
 2. Commission Action
 - D. Liability Under Rules 9j–1(b) and (c)
 1. Proposed Approach
 2. Commission Action
 - a. Rule 9j–1(b)
 - b. Rule 9j–1(c)
 - E. Safe Harbors and Affirmative Defenses
 1. Proposed Approach
 2. Commission Action
 - a. Affirmative Defense: Binding Contractual Obligations
 - b. Affirmative Defense: Policies and Procedures
 - c. Proposed Safe Harbor: Compression
 - d. Other Requested Safe Harbors and Affirmative Defenses
 - III. Rule 15fh–4(c): Preventing Undue Influence Over Chief Compliance Officers; Policies and Procedures Regarding Compliance With Rule 9j–1 and Rule 15fh–4(c)
 - A. Proposed Approach
 - B. Commission Action
 - IV. Paperwork Reduction Act
 - V. Economic Analysis
 - A. Introduction
 - B. Broad Economic Considerations
 - C. Baseline

1. Existing Regulatory Frameworks
 2. Security-Based Swap Data, Market Participants, Dealing Structures, and Levels of Security-Based Swap Trading Activity
 - D. Benefits and Costs of Rule 9j–1
 1. Benefits
 2. Costs
 - E. Benefits and Costs of Rule 15fh–4(c)
 1. Benefits
 2. Costs
 - F. Effects on Efficiency, Competition, and Capital Formation
 1. Competition
 2. Efficiency
 3. Capital Formation
 - G. Reasonable Alternatives
 1. Narrow the Scope of Rule 9j–1
 2. Safe Harbors
 - a. Safe Harbor for Hedging Exposure Arising Out of Lending Activities
 - b. Safe Harbors for Lender Disclosure, Centralized Market Activities, and Legitimate Restructurings
 - c. Safe Harbor for Publicly Executed Strategies
 - d. Elimination of All Safe Harbors and Affirmative Defenses
 3. Implementing a More Prescriptive Approach in Rule 9j–1
 4. Separate Rules for CDS and Equity Security-Based Swaps
 5. Exclude Underlying Securities
 6. Limit Activities Prohibited Under Rule 15fh–4(c)
 - VI. Regulatory Flexibility Act Certification
 - VII. Other Matters
- Statutory Authority

I. Introduction

A. Background

Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”)¹ provided the Commission with primary responsibility for regulating security-based swaps. A person who satisfies the definitions of “security-based swap dealer” or “major security-based swap participant” is required to register with the Commission in such capacity and is therefore subject to the Commission’s regime regarding, among other things, internal supervision requirements and the requirement to designate an individual to serve as the CCO.² In addition to other requirements, the CCO must take reasonable steps to ensure that the SBS Entity establishes, maintains, and reviews written policies

¹ Wall Street Transparency and Accountability Act of 2010, Public Law 111–203, sections 761–774, 124 Stat. 1376, 1754–1802 (2010). Unless otherwise indicated, references to “Title VII” in this release are to subtitle B of title VII of the Dodd-Frank Act.

² See, e.g., 17 CFR 240.3a71–1 (Definition of “security-based swap dealer”); 17 CFR 240.3a71–2 (De minimis exception for SBSD registration); 17 CFR 240.3a67–1 (Definition of “major security-based swap participant”); 17 CFR 240.15Fb2–1 (Registration of SBSDs and MSBSPs); 17 CFR 240.15Fb–3 (Business conduct requirements for SBSDs and MSBSPs).

and procedures reasonably designed to achieve compliance with the Exchange Act and the rules and regulations thereunder relating to its business as an SBS Entity.³

The Dodd-Frank Act also amended the Exchange Act in a number of important ways to prohibit fraud, manipulation, and deception in connection with security-based swaps. In particular, section 763(g) of the Dodd-Frank Act expanded the anti-manipulation provisions of section 9 of the Exchange Act to encompass purchases or sales of security-based swaps and requires the Commission to adopt rules to prevent fraud, manipulation, and deception in connection with security-based swaps.⁴ Specifically, paragraph (j) of section 9 makes it unlawful for “any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange, to effect any transaction in, or to induce or attempt to induce the purchase or sale of, any security-based swap, in connection with which such person engages in any fraudulent, deceptive, or manipulative act or practice, makes any fictitious quotation, or engages in any transaction, practice, or course of business which operates as a fraud or deceit upon any person.”⁵ It also provides that the Commission “shall . . . by rules and regulations define, and prescribe means reasonably designed to prevent, such transactions, acts, practices, and courses of business as are fraudulent, deceptive, or manipulative, and such quotations as are fictitious.”⁶

Additionally, section 761 of the Dodd-Frank Act modified several definitions in both the Exchange Act and the Securities Act of 1933 (“Securities Act”) to account for security-based swaps.⁷ For example, the Dodd-Frank Act amended the definition of “security” in section 3(a)(10) of the Exchange Act⁸ and section 2(a)(1) of the Securities Act⁹ to include security-based swaps. As a result, security-based swaps, because they are securities, are subject to the general antifraud and anti-

manipulation provisions of the Federal securities laws, including sections 9(a) and 10(b) of the Exchange Act, and 17 CFR 240.10b-5 (“Rule 10b-5”) thereunder,¹⁰ and section 17(a) of the Securities Act.¹¹

Moreover, the Dodd-Frank Act amended the definitions of “purchase” and “sale” in section 2(a)(18) of the Securities Act,¹² the definitions of “buy” and “purchase” in section 3(a)(13) of the Exchange Act,¹³ and “sale” and “sell” in section 3(a)(14) of the Exchange Act,¹⁴ in the context of security-based swaps, to include the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of rights or obligations under, a security-based swap, as the context may require. As a result of those changes, misconduct in connection with these actions is also prohibited under sections 9 and 10(b) of the Exchange Act, and Rule 10b-5 thereunder, and section 17(a) of the Securities Act.

On December 15, 2021, the Commission re-proposed antifraud and anti-manipulation rules,¹⁵ as required by section 9(j) of the Exchange Act. The re-proposal followed the Commission’s adoption of much of its Title VII rulemaking related to security-based swaps,¹⁶ as well as developments in the

security-based swap market, including manufactured credit events or other opportunistic strategies in the credit default swap (“CDS”) market, as discussed in section I.B below.¹⁷ In addition, in recognition of the fact that CCOs of SBS Entities play an important role in preventing fraud and manipulation by SBS Entities and their personnel, the Commission proposed an additional measure under section 15F(h) of the Exchange Act¹⁸ to protect CCOs in the furtherance of those duties.¹⁹ The Commission is adopting Rule 9j-1 with modifications in response to commenters,²⁰ and adopting Rule 15fh-4(c) as proposed.²¹ In developing this rulemaking we have consulted and

related to swaps, including the adoption of antifraud and anti-manipulation rules. See 2021 Proposing Release, 87 FR at 6654–55, 6654 n.19.

¹⁷ See *infra* section I.B.2, describing in more detail manufactured credit events and other opportunistic strategies in the CDS market. See also 2021 Proposing Release, 87 FR at 6654–55. Additionally, in section II.C.2, *infra*, the Commission addresses concerns raised by commenters with regard to the application of Rule 9j-1 to legitimate credit activity or other activity in connection with security-based swap transactions, some of which may fit the descriptions of the manufactured credit events and other opportunistic strategies described in the 2021 Proposing Release.

¹⁸ See 15 U.S.C. 78o-10(h).

¹⁹ See 2021 Proposing Release, 87 FR at 6664–65. To be clear, the ultimate responsibility for compliance by the SBS Entity with the Federal securities laws, including the requirement to have adequate compliance systems and to avoid violations generally, rests with the SBS Entity itself.

²⁰ The comment letters are available at <http://www.sec.gov/comments/s7-32-10/s73210.shtml>. The Commission also received comments on topics outside the scope of the proposal that are not addressed in this release. See, e.g., Comment from Anonymous, dated Feb. 6, 2022, available at <https://www.sec.gov/comments/s7-32-10/s73210-20114041-266299.htm> (discussing dark pools); Comment from Anonymous, dated Dec. 16, 2021, available at <https://www.sec.gov/comments/s7-32-10/s73210-20109790-264127.htm> (discussing securities lending).

²¹ As described in greater detail below, the Commission is making several changes to proposed Rule 9j-1 and adopting Rule 15fh-4(c) as proposed. First, the Commission is revising paragraph (a) to more closely track the language of section 9(j) of the Exchange Act with regard to the conduct subject to the prohibitions of final Rule 9j-1(a), moving the prohibitions on attempted conduct from paragraphs (a)(3) and (a)(4) to a new paragraph (a)(5), and clarifying that the Commission believes scienter is the proper standard to apply to violations of paragraph (a)(5). See *infra* sections II.A and II.B. In addition, the Commission is moving paragraph (b) of proposed Rule 9j-1 to a new paragraph (a)(6) to rely on the scope of conduct subject to the prohibitions of paragraph (a). See *infra* section II.C. Finally, the Commission is adopting two affirmative defenses to violations of Rule 9j-1, one for actions taken in connection with binding rights and obligations under security-based swap documentation and one for appropriate policies and procedures to ensure compliance with Rule 9j-1 such as restrictions on access to material nonpublic information. See *infra* sections II.E.2.a and II.E.2.b. The Commission is not adopting the proposed safe harbor for portfolio compression exercises. See *infra* section II.E.2.c.

¹⁰ 15 U.S.C. 78j(b).

¹¹ 15 U.S.C. 77q(a).

¹² 15 U.S.C. 77b(a)(18).

¹³ 15 U.S.C. 78c(a)(13).

¹⁴ 15 U.S.C. 78c(a)(14).

¹⁵ See Prohibition Against Fraud, Manipulation, or Deception in Connection with Security-Based Swaps; Prohibition against Undue Influence over Chief Compliance Officers; Position Reporting of Large Security-Based Swap Positions, Exchange Act Release No. 93784 (Dec. 15, 2021), 87 FR 6652 (Feb. 4, 2022) (“2021 Proposing Release”). See also Prohibition Against Fraud, Manipulation, and Deception in Connection with Security-Based Swaps, Exchange Act Release No. 63236 (Nov. 3, 2010), 75 FR 68560 (Nov. 8, 2010) (“2010 Rule 9j-1 Proposing Release”). For purposes of this release, we will refer to the version of Rule 9j-1 that the Commission proposed in the 2010 Rule 9j-1 Proposing Release as the “2010 Proposed Rule.” We will refer to re-proposed Rule 9j-1 as “proposed rule” or “re-proposed Rule 9j-1” and to final Rule 9j-1 as “Rule 9j-1,” “final rule,” or “final Rule 9j-1.”

¹⁶ As more fully described in the 2021 Proposing Release, the Commission has now completed a majority of its rulemaking under Title VII, SBS Entities are required to register with the Commission (as of June 7, 2023, there are 50 conditionally registered security-based swap dealers), and all persons are required to report their security-based swap transactions to security-based swap data repositories. See 2021 Proposing Release, 87 FR at 6653 nn.2–4 and accompanying text. Further, since 2010, regulators overseeing the world’s primary over-the-counter (“OTC”) derivatives markets have made significant progress implementing reforms for OTC derivatives and the Commodity Futures Trading Commission (“CFTC”) has largely completed its Title VII rulemakings

³ See 17 CFR 240.15Fk-1; Business Conduct Standards for Security-Based Swap Dealers and Major Security-Based Swap Participants, Exchange Act Release No. 77617 (Apr. 14, 2016), 81 FR 29960 (May 13, 2016) (“Business Conduct Standards Adopting Release”).

⁴ See 15 U.S.C. 78i(j).

⁵ See *id.* Note that section 9 of the Exchange Act erroneously contains two subsection (j)s.

⁶ See *id.*

⁷ Section 3(a)(68) of the Exchange Act defines “security-based swap.” 15 U.S.C. 78c(a)(68).

⁸ 15 U.S.C. 78c(a)(10).

⁹ 15 U.S.C. 77b(a)(1).

coordinated with the CFTC and the prudential regulators in accordance with section 712(a)(2) of the Dodd-Frank Act.²² Nothing in Rule 9j–1 alters the application of sections 9(a) and 10(b) of the Exchange Act, and Rule 10b–5 thereunder, and section 17(a) of the Securities Act, including to misconduct that is in connection with the exercise of any right or performance of any obligation under the security-based swap.

The Commission also proposed for comment a new Rule 10B–1,²³ which would require any person with a security-based swap position that exceeds a certain threshold to promptly file with the Commission a schedule disclosing certain information related to its security-based swap positions. The Commission is not finalizing Rule 10B–1 in this release as it continues to consider comments received in connection with proposed Rule 10B–1.

B. Overview of Security-Based Swaps

1. Security-Based Swaps Generally

Although the definition of security-based swap is detailed and comprehensive,²⁴ at its most basic level, a security-based swap is an agreement, contract, or transaction in which two parties agree to the exchange of payments or cash flows based upon the value of other assets or upon the occurrence or non-occurrence of some event, including, for example, a change in a stock price or the occurrence of some type of credit event.²⁵ The

exchange of these payments or deliveries, including purchases or sales upon certain events, is a fundamental aspect or feature of a security-based swap.²⁶ Moreover, this feature of security-based swaps is in contrast to secondary market transactions involving equity or debt securities where the completion of a purchase or sale transaction terminates the mutual obligations of the parties. Security-based swap counterparties, who are considered the issuers of the security-based swaps, continue to have obligations to one another throughout the life of the instrument, which can extend for years if not decades.²⁷

Parties may enter into a security-based swap for a multitude of reasons, but often, the parties to the contract seek to gain exposure to an asset without owning it or to manage or transfer risks in their asset and liability portfolios (e.g., credit or equity risks). Typical participants in the security-based swap market include, among others, lenders transferring credit risk,²⁸ insurance companies managing asset and liability risk specific to the insurance industry,²⁹ activists or hedge funds obtaining exposure to the price movement and dividend payments of a stock without the costs and burdens of stock ownership,³⁰ and financial institutions that engage in market-making and

occurrence of a specific event, between the parties during the life of a security-based swap.

²⁶ The definition of security-based swap requires that the instrument first meet the definition of swap in section 1a(47) of the Commodity Exchange Act. See 15 U.S.C. 78c(a)(68); *supra* note 25. That definition provides, *inter alia*, that a swap is an agreement, contract, or transaction that provides for any purchase, sale, payment, or delivery upon the occurrence or nonoccurrence of certain events or that provides on an executory basis for an exchange on a fixed or contingent basis, of one or more payments that meet certain conditions. See 7 U.S.C. 1a(47)(ii) and (iii).

²⁷ See Further Definition of “Swap Dealer,” “Security-Based Swap Dealer,” “Major Swap Participant,” “Major Security-Based Swap Participant” and “Eligible Contract Participant,” Exchange Act Release No. 66868 (Apr. 27, 2012), 77 FR 30596, 30616–17 (May 23, 2012) (“In contrast to a secondary market transaction involving equity or debt securities, in which the completion of a purchase or sale transaction can be expected to terminate the mutual obligations of the parties to the transaction, the parties to a security-based swap often will have an ongoing obligation to exchange cash flows over the life of the agreement.”).

²⁸ See, e.g., Letter from Elliot Ganz, Loan Syndications and Trading Association (“LSTA”), dated Mar. 17, 2022 (“LSTA Letter”), at 2–3.

²⁹ See Letter from Michael Lovendusky, American Council of Life Insurers (“ACLI”), dated Mar. 21, 2022 (“ACLI Letter”).

³⁰ See Letter from Richard B. Zabel, Elliott Investment Management L.P., dated Mar. 21, 2022 (addressing concerns related to proposed Rule 10B–1 but also describing the security-based swap activity of activists and hedge funds).

dealing in security-based swaps.³¹ The terms of the contract between the counterparties determine the specific rights and obligations of the parties throughout the life of the security-based swap, including, for example, the amount and timing of periodic payments due under the instrument, the maturity of the instrument, and terms of settlement. Counterparties to a security-based swap typically use a standardized agreement published by ISDA, first in 1992 and updated in 2002, which is the most widely used contract setting forth the terms of security-based swap transactions (the “ISDA Master Agreement”). Unlike other types of securities where settlement occurs when the buyer receives the security purchased and the seller receives cash equaling the value of the security sold, for security-based swaps, a final net payment is paid by one party to the other at a future point in time to which the parties have contractually agreed.³²

Two common examples of security-based swaps—credit default swaps (“CDS”) and total return swaps (“TRS”)—are described in more detail below.³³

Generally, a CDS is a contract in which a party (the “protection buyer”), such as a lender, agrees to make periodic payments (the “premium”) over an agreed upon time period to another party (the “protection seller”) in exchange for a payment from the protection seller in the event of default by an issuer (or group of issuers) of securities (the “reference entity”).³⁴ The

³¹ See Letter from Bridget Polichene, Institute of International Bankers (“IIB”), Scott O’Malia, International Swaps and Derivatives Association (“ISDA”), and Kenneth E. Bensten, Jr., Securities Industry and Financial Markets Association (“SIFMA”), dated Mar. 21, 2022 (“IIB-ISDA-SIFMA Letter”).

³² See, e.g., Shortening the Securities Transaction Settlement Cycle, Exchange Act Release No. 96939 (Feb. 15, 2023), 88 FR 13872, 13878 (Mar. 6, 2023) (“T+1 Adopting Release”) (citing letter from Thomas Price, Managing Director, and Lindsey Weber Keljo, Head—Asset Management Group, Securities Industry and Financial Markets Association re: File No. S7–05–22 (Apr. 13, 2022), at 11).

³³ The definition of security-based swap in the Exchange Act and the rules thereunder is broad. See *supra* notes 25–26 and related discussion. The application of the rules we adopt in this document is not limited to CDS and TRS or to transactions between particular types of counterparties.

³⁴ A CDS generally falls within the second prong of the definition of a swap under section 1(a) of the Commodity Exchange Act as a contract “that provides for any purchase, sale, payment, or delivery (other than a dividend on an equity security) that is dependent on the occurrence, nonoccurrence, or the extent of the occurrence of an event or contingency associated with a potential financial, economic, or commercial consequence.” See 7 U.S.C. 1a(47)(a)(ii). If the CDS falls within any of the prongs of the definition of security-based swap in Exchange Act section 3(a)(68)(A)(ii), the

²² In addition, in accordance with section 752 of the Dodd-Frank Act, the Commission has consulted and coordinated with foreign regulatory authorities through Commission staff participation in numerous bilateral and multilateral discussions with foreign regulatory authorities addressing the regulation of OTC derivatives markets.

²³ See 2021 Proposing Release, 87 FR at 6667–76.

²⁴ See 15 U.S.C. 78c(a)(68) (defining “security-based swap”). See also Further Definition of “Swap,” “Security-Based Swap,” and “Security-Based Swap Agreement”; Mixed Swaps; Security-Based Swap Agreement Recordkeeping, Exchange Act Release No. 67453 (July 18, 2012), 77 FR 48208, 48211 (Aug. 13, 2012) (“Product Definitions Release”) (further defining certain terms related to the definition of “security-based swap”).

²⁵ See generally section 3(a)(68) of the Exchange Act, which defines a “security-based swap” as any agreement, contract, or transaction that is a swap as defined in section 1(a) of the Commodity Exchange Act that is based on a narrow-based security index, or a single security or loan, or any interest therein or on the value thereof, or the occurrence or non-occurrence of an event relating to a single issuer of a security or the issuers of securities in a narrow-based security index, provided that such event directly affects the financial instruments, financial condition, or financial obligations of the issuer. 15 U.S.C. 78c(a)(68). See also 2010 Rule 9j–1 Proposing Release, 75 FR at 68561 (generally discussing the definition of “security-based swap”). This section also discusses examples of security-based swaps and the exchange of payments or deliveries, or the purchase or sale or other payments upon the

CDS contract states whether the CDS is settled physically or in cash in the event of default by the reference entity. Generally, the protection buyer is using the CDS to manage risk and the protection seller is using the CDS to take on risk in return for a premium. A cash-settled CDS contract relying on ISDA documentation is subject to determinations by a committee with respect to whether a defined default event (a “credit event”) has occurred and, if so, to hold an auction to determine the settlement price of the CDS. The auction process includes the determination and publication of a list of deliverable obligations that a CDS protection buyer can deliver to the CDS protection seller after the auction settlement. A CDS protection buyer can deliver any of the obligations on the list, with delivery of the cheapest deliverable obligation maximizing recovery.³⁵ This feature of CDS contracts is an aspect of some of the manufactured or opportunistic strategies discussed in section I.B.2.

In contrast, a TRS may obligate one of the parties (*i.e.*, the total return payer) to transfer the total economic performance (*e.g.*, income from interest and fees, gains or losses from market movements, and credit losses) of a reference asset (*e.g.*, a debt or equity

security) (the “reference underlying”), in exchange for a specified or fixed or floating cash flow (including payments for any principal losses on the reference asset) from the other party (*i.e.*, the total return receiver).³⁶ If the TRS is negotiated over-the-counter, the terms of the TRS can be individually negotiated and could include one payment at the expiration of the TRS or might include a series of payments on periodic interim settlement dates over the tenor of the TRS. For TRS with periodic interim settlement dates counterparties could agree to reset the price of the reference underlying on the periodic interim settlement date based on current market prices of the reference underlying (“reference price”). Accordingly, throughout the life of a TRS, depending on the terms of the TRS, the reference price that determines that payment on periodic interim settlement dates might be reset based on current market prices of the reference underlying.

2. Security-Based Swap Market Developments

In 2010, following the 2008 financial crisis, Congress enacted the Dodd-Frank Act “to promote the financial stability of the United States by improving accountability and transparency in the financial system.”³⁷ Title VII of the Dodd-Frank Act addressed significant issues and risks in the swap and security-based swap markets, which had experienced dramatic growth leading up to the 2008 financial crisis and were shown to be capable of affecting significant sectors of the U.S. economy.³⁸ In testimony before Congress introducing the first draft of the Dodd-Frank Act, Treasury Secretary Timothy Geithner highlighted the risks posed by an unregulated OTC derivatives market, which had been operating without the “basic protections and oversight” existing in the rest of the financial systems, including a “limited ability to police fraud and

manipulation.”³⁹ In his written testimony, Secretary Geithner listed four broad objectives of the proposed reforms which were eventually enacted as Title VII of the Dodd-Frank Act: (1) preventing activities in the OTC derivatives markets from posing risk to the stability of the financial system; (2) promoting efficiency and transparency of the OTC derivatives markets; (3) preventing market manipulation, fraud, and other abuses; and (4) protecting consumers and investors by ensuring that OTC derivatives are not marketed inappropriately to unsophisticated parties.⁴⁰ Secretary Geithner also stressed that the CFTC and the SEC should be provided with strong authority for civil enforcement and regulation of fraud, market manipulation, and other abuses in the OTC derivative markets.⁴¹ The authority enacted in Title VII of the Dodd-Frank Act includes, but is not limited to, Exchange Act section 9(j). Ensuring that the Commission has the necessary tools to police the security-based swap markets is a key component to ensure that Title VII’s reforms are not undermined.

The security-based swap market remains large. Based on information reported pursuant to 17 CFR 242.900 to 242.909 (“Regulation SBSR”), as of November 25, 2022, the gross notional amount outstanding in the security-based swap market is approximately \$8.5 trillion across the credit, equity, and interest rate asset classes.⁴² The credit security-based swap asset class is large, with a gross notional amount of approximately \$4.7 trillion, of which single-name CDS (including corporate and sovereign) account for the largest category at \$4.3 trillion.⁴³ Additionally, as indicated by data submitted pursuant to Regulation SBSR, the size of the equity security-based swap market is also significant—with approximately \$3.6 trillion of equity security-based swaps outstanding as of November 25, 2022.⁴⁴

In general, the ongoing payments of a security-based swap depend, in part, on

CDS would be a security-based swap. See Product Definitions Release, 77 FR at 48267, and the broader discussion of CDS therein.

³⁵ See 2021 Proposing Release, 87 FR at 6655 n.23. As described in the 2021 Proposing Release, in order to cash settle any CDS contract that relies on the ISDA standard documentation, a Credit Derivatives Determinations Committee (“DC”) must make a determination that a credit event occurred and vote to hold an auction to determine the settlement price of the CDS. A DC is generally composed of nine or ten dealers and five buy-side members. Once a DC determines that a credit event has occurred and that an auction should be held, the DC Secretary publishes auction terms, which include a list of obligations that a CDS protection buyer can deliver to the CDS protection seller after the auction settlement (each a “deliverable obligation”). Each auction consists of two parts: (1) the first part of the auction, which involves submission of physical settlement requests by participating dealers, aims at determining the initial market mid-point, the net open interests, and adjustment amounts; and (2) the second part of the auction consists of calculating the final settlement price. As noted, protection buyers are incentivized to deliver into the auction the cheapest deliverable obligation, as it maximizes their recovery; as a result, the value of this “cheapest to deliver” deliverable obligation drives the final settlement price. See Markit and Creditex Credit Event Auction Primer, 1 (Feb. 2010), available at http://www.creditfixings.com/information/affiliations/fixings/auctions/docs/credit_event_auction_primer.pdf. See also Credit Suisse, A Guide to Credit Events and Auctions, 5 (Jan. 11, 2012), available at https://doc.research-andanalytics.csfb.com/docView?language=ENG&source=emfromsendlink&format=PDF&document_id=803733390&serialid=FWHCx3yCrSE3FoEvAbEKa6fRKhqLoKs0jL1gR5W2Dfs%3D.

³⁶ See 2010 Rule 9j–1 Proposing Release, 75 FR at 68562. See also *infra* section V.B, discussing broad economic considerations of security-based swaps and specifically TRS.

³⁷ Dodd-Frank Act, Public Law 111–203, Preamble. See also Business Conduct Standards Adopting Release, 81 FR at 29961.

³⁸ Business Conduct Standards Adopting Release, 81 FR at 29961. See also Cross-Border Security-Based Swap Activities: Re-Proposal of Regulation SBSR and Certain Rules and Forms Relating to the Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants, Exchange Act Release No. 69490 (May 1, 2013), 78 FR 30967, 30980 (May 23, 2013) (“Cross-Border Release”) (discussing the spillover and contagion effects arising from security-based swap transactions in the context of American International Group, Inc., and its subsidiary AIG Financial Products Corp.).

³⁹ Senate Hearing on Over the Counter Derivatives Reform and Addressing Systemic Risks, S. Hrg. 1111–803 (Dec. 2, 2009), available at <https://www.govinfo.gov/content/pkg/CHRG-111shrg62722/pdf/CHRG-111shrg62722.pdf>.

⁴⁰ *Id.* (including testimony noting that enacted reforms will result in “very consequential changes” to OTC derivatives markets).

⁴¹ *Id.*

⁴² See Report on Security-Based Swaps, Mar. 20, 2023, available at <https://www.sec.gov/files/report-security-based-swaps-032023.pdf> (“SBS Report”). For further discussion of the Regulation SBSR data, see *infra* section V.C.2.

⁴³ See *id.*

⁴⁴ See *id.*

its gross notional amount outstanding.⁴⁵ The particular aspects and characteristics of security-based swaps (described above in section I.B.1) provide opportunities and incentives for misconduct. In general, parties to a security-based swap may engage in misconduct in connection with the security-based swap (including in the reference underlying of such security-based swap) to trigger, avoid, or affect the value of ongoing payments or deliveries. For instance, a party faced with significant risk exposure may engage or attempt to engage in manipulative or deceptive conduct that increases or decreases the value of payments or cash flow under a security-based swap relative to the value of the reference underlying, including the price or value of a deliverable obligation under a security-based swap. Moreover, fraud and manipulation in connection with a security-based swap can affect not just a direct counterparty, but also counterparties to that counterparty. For example, if fraud or manipulation leads to a large change in variation margin, the defrauded counterparty could default on its obligations to its other counterparties. In addition, other counterparties to the same security-based swaps could be affected by fraud or manipulation that affects the reference underlying assets, as could investors in those underlying assets. Given the global and interconnected nature of the security-based swap markets, it is critical that the Commission has appropriate tools to fight fraud and manipulation in these markets.⁴⁶ Recent developments in the security-based swap market highlight these concerns. For example, in the 2021 Proposing Release, the Commission discussed certain manufactured or other opportunistic CDS strategies that had been reported by academics and the press:⁴⁷

- A CDS buyer working with a reference entity to create an artificial, technical, or temporary failure-to-pay

credit event in order to trigger a payment on a CDS to the buyer (and to the detriment of the CDS seller).⁴⁸

- Alone or in combination with the above or other strategies, causing the reference entity to issue a below-market debt instrument in order to artificially increase the auction settlement price for the CDS (i.e., by creating a new “cheapest to deliver” deliverable obligation).⁴⁹

- CDS buyers endeavoring to influence the timing of a credit event in order to ensure a payment (upon the triggering of the CDS) before expiration of a CDS, or a CDS seller taking similar actions to *avoid* the obligation to pay by ensuring a credit event occurs after the expiration of the CDS, or taking actions to limit or expand the number and/or kind of deliverable obligations in order to impact the recovery rate.⁵⁰

- CDS sellers offering financing to restructure a reference entity in such a way that “orphans” the CDS—eliminating or reducing the likelihood of a credit event by moving the debts off the balance sheets of the reference entity and onto the balance sheets of a subsidiary or an affiliate that is not referenced by the CDS.⁵¹

- Taking actions, including as part of a larger restructuring, to increase (or decrease) the supply of deliverable obligations by, for example, adding (or removing) a co-borrower to existing debt of a reference entity, thereby increasing (or decreasing) the likelihood of a credit event and the cost of CDS.⁵²

The 2021 Proposing Release also discussed the fact that in 2019, the former SEC Chairman issued a joint public statement with the principals of the CFTC and the U.K. Financial Conduct Authority at the time stating that the “continued pursuit of various opportunistic strategies in the credit derivatives markets . . . may adversely affect the integrity, confidence and reputation of the credit derivatives

markets, as well as markets more generally.”⁵³

Taking into consideration all of the above, Rule 9j–1 will be an important additional tool to augment the Commission’s oversight of the security-based swap markets including, but not limited to, the markets for CDS and TRS.

B. Overview of the Final Rules

1. Rule 9j–1

As described in detail below, final Rule 9j–1 includes prohibitions on categories of misconduct prohibited by section 10(b) of the Exchange Act, and Rule 10b–5 thereunder, and section 17(a) of the Securities Act, when effecting any transaction in, or attempting to effect any transaction in, any security-based swap, or when purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, any security based-swap).⁵⁴ The final rule also includes a provision prohibiting the manipulation or attempted manipulation of the price or valuation of any security-based swap, including any payment or delivery related thereto. This provision has been moved to paragraph (a)(6) of Rule 9j–1 (from paragraph (b) as proposed) to clarify that these provisions apply to conduct that is undertaken in connection with directly or indirectly effecting, or attempting to effect, any transaction in any security-based swap, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap.⁵⁵ Further, final Rule 9j–1 provides that: (1) a person with material nonpublic information about a security cannot avoid liability under the securities laws by communicating about or making purchases or sales in the security-based swap (as opposed to communicating about or purchasing or selling the underlying security); and (2) a person cannot avoid liability under section 9(j) or Rule 9j–1 in connection with a fraudulent scheme involving a security-based swap by instead making purchases or sales in the underlying

⁴⁵ See, e.g., *Bloomberg L.P. v. Commodity Futures Trading Com’n*, 949 F. Supp. 2d 91, 96 (D.D.C. 2013) (stating that a swap “is a contract that typically involves an exchange of one or more payments based on the underlying value of a notional amount of one or more commodities, or other financial or economic interest” (emphasis added)).

⁴⁶ See Application of “Security-Based Swap Dealer” and “Major Security-Based Swap Participant” Definitions to Cross-Border Security-Based Swap Activities, Exchange Act Release No. 72472 (June 25, 2014), 79 FR 47278, 47283 (Aug. 12, 2014) (discussing the global nature and interconnectedness of the security-based swap market and the potential for risk transmission).

⁴⁷ 2021 Proposing Release, 87 FR at 6655. See also *supra* note 35 and related discussion regarding the operation of CDS auctions.

⁴⁸ See Henry T.C. Hu, Corporate Distress, Credit Default Swaps, and Defaults: Information and Traditional, Contingent, and Empty Creditors, 13 *Brook. J. Corp. Fin. & Com. L.* 5–32, at 26–27 (Nov. 2018), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3302816.

⁴⁹ See Statement on Manufactured Credit Events by CFTC Divisions of Clearing and Risk, Market Oversight, and Swap Dealer and Intermediary Oversight (Apr. 24, 2018), available at <https://www.cftc.gov/PressRoom/SpeechesTestimony/divisionsstatement042418>.

⁵⁰ See Hu, *supra* note 48 at 22–26.

⁵¹ See Gina-Gail S. Fletcher, Engineered Credit Default Swaps: Innovative or Manipulative?, 94 *N.Y.U. L. Rev.* 1073, 1101 (2019).

⁵² See Fletcher, *supra* note 51 at 1098. See also CFTC Talks Podcast, Credit Derivatives, (Jul. 10, 2019), available at <https://www.cftc.gov/Exit/index.htm?https://youtu.be/Qqo9KR6JXaM?>

⁵³ See Joint Statement on Opportunistic Strategies in the Credit Derivatives Market (June 24, 2019), available at <https://www.sec.gov/news/press-release/2019-106> (“2019 Joint Statement”); 2021 Proposing Release, 87 FR at 6655.

⁵⁴ See Rules 9j–1(a), (a)(1) through (a)(5), and (d).

⁵⁵ See Rule 9j–1(a)(6).

security (as opposed to purchases or sales in the security-based swap).⁵⁶ In addition, final Rule 9j–1 includes two affirmative defenses from the liability under paragraphs (a)(1) through (5) of Rule 9j–1: (1) where the action otherwise prohibited by Rule 9j–1 was taken pursuant to binding rights and obligations in written security-based swap documentation so long as the security-based swap was entered into, or the amendment was made, before the person became aware of the material nonpublic information, and in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 9j–1; and (2) with respect to entities, if the entity demonstrates that the individual at the entity making the investment decision was not aware of material nonpublic information and the entity had implemented reasonable policies and procedures to prevent violations of Rules 9j–1(a)(1) through (5).⁵⁷

2. Rule 15fh–4(c)

The Commission also is adopting a rule aimed at protecting the independence and objectivity of an SBS Entity's CCO by preventing the personnel of an SBS Entity from taking actions to coerce, mislead, or otherwise interfere with the CCO. The Commission recognizes that SBS Entities dominate the security-based swap market and also recognizes the important role that CCOs of SBS Entities play in ensuring compliance by SBS Entities and their personnel with the Federal securities laws. As a result, the Commission is adopting Rule 15fh–4©, which makes it unlawful for any officer, director, supervised person, or employee of an SBS Entity, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the SBS Entity's CCO in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.⁵⁸

II. Rule 9j–1: Prohibition Against Fraud, Manipulation, and Deception in Connection With Security-Based Swaps

Final Rule 9j–1 will aid the Commission in its pursuit of actions that directly target misconduct that reaches security-based swaps. The rule takes into account the features of a security-based swap and the broad definitions of “purchase” and “sale” in the Securities Act,⁵⁹ and of “buy,” “purchase,” “sale,” and “sell” in the Exchange Act,⁶⁰ to include the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security-based swap, as the context may require. Final Rule 9j–1 applies to fraudulent, deceptive, or manipulative misconduct related to the exercise of any right or performance of any obligation under a security-based swap if such misconduct occurs in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, a security-based swap.⁶¹ For example, to the extent that such misconduct results in the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security-based swap, as the context may require, Rule 9j–1 would apply. In adopting Rule 9j–1, the Commission continues to recognize the regulatory and market developments that supported the proposal of an antifraud and anti-manipulation provision.⁶²

In general, fraudulent, deceptive, or manipulative conduct, such as providing false or incomplete information to a counterparty to secure better terms or pricing or to alter the performance of ongoing rights and obligations, has the potential to harm counterparties to all forms of security-based swaps, including CDS, equity security-based swaps, and non-CDS debt security-based swaps. Manipulation of the reference underlying security can affect the pricing of an equity or debt security-based swap, as well as the ongoing payments and obligations that are based on the value of that reference security. Further, in some cases, particularly in instances involving security-based swap transactions that

are effected over the internet, there is a potential for trading software to distort pricing and payouts on security-based swaps.⁶³ Finally, to the extent a CDS-related opportunistic strategy alters the operations of a reference entity, shareholders in reference underlying entities and counterparties to any security-based swap based on that reference entity could be impacted; the potential harm is not limited to CDS holders or to the counterparties of bad actors.

A. Misconduct “In Connection With” “Purchases,” “Sales,” or “Effecting Transactions”

1. Proposed Approach

As proposed, Rule 9j–1 would have prohibited the same categories of misconduct addressed by section 10(b) of the Exchange Act,⁶⁴ and Rule 10b–5 thereunder,⁶⁵ as well as section 17(a) of the Securities Act.⁶⁶ The proposed rule imposed liability for misconduct related to any ongoing payments and deliveries that are typical of security-based swaps and which occur throughout the life of the security-based swap.⁶⁷ Specifically, proposed Rule 9j–1(a) would have made it unlawful for any person, directly or indirectly, to purchase or sell, or attempt to induce the purchase or sale of, any security-based swap; to effect any transaction in, or attempt to effect any transaction in, any security-based swap; to take any action to exercise any right, or any action related to performance of any obligation, under any security-based swap, including in connection with any payments, deliveries, rights, or obligations or alterations of any rights thereunder; or to terminate (other than on its scheduled maturity date) or settle any security-based swap, in connection with which such person: (1) employs or attempts to employ any device, scheme,

⁶³ See, e.g., SEC Investor Alert: Binary Options Fraud, available at <https://www.investor.gov/protect-your-investments/fraud/types-fraud/binary-options-fraud> (“SEC Binary Options Fraud Alert”) (stating that the SEC has received numerous complaints alleging that certain “internet-based binary options trading platforms manipulate the trading software to distort binary options prices and payouts”). The SEC Binary Options Fraud Alert represents the views of the staff of the Office Investor Education and Advocacy. It is not a rule, regulation, or statement of the Commission. The Commission has neither approved nor disapproved its content. The SEC Binary Options Fraud Alert, like all staff statements, has no legal force or effect: it does not alter or amend applicable law, and it creates no new or additional obligations for any person. Depending on the facts and circumstances, binary options based on securities may be security-based swaps.

⁶⁴ 15 U.S.C. 78j(b).

⁶⁵ 17 CFR 240.10b–5.

⁶⁶ 15 U.S.C. 77q(a).

⁶⁷ See 2021 Proposing Release, 87 FR at 6661–62.

⁵⁶ See Rules 9j–1(b) and (c).

⁵⁷ See Rule 9j–1(e).

⁵⁸ The Commission also amends the CFR designation of Rule 15Fh–4 in order to ensure the regulatory text conforms more consistently with section 2.13 of the Document Drafting Handbook. See Office of the Federal Register, Document Drafting Handbook (Aug. 2018 Edition, Revision 1.4, dated Jan. 7, 2022), available at <https://www.archives.gov/files/federal-register/write/handbook/ddh.pdf>. In particular, the Commission amends the CFR section designation for 17 CFR 240.15Fh–4 (Rule 15Fh–4) to replace the uppercase letter with the corresponding lowercase letter, such that the rule is redesignated as 17 CFR 240.15fh–4 (Rule 15fh–4).

⁵⁹ 15 U.S.C. 77b(a)(18).

⁶⁰ 15 U.S.C. 78c(a)(13) and (14).

⁶¹ See *supra* section I.B.1 for a discussion regarding ongoing payments and deliveries that are typical for a security-based swap.

⁶² See *supra* section I.B.2.

or artifice to defraud or manipulate; (2) makes or attempts to make any untrue statement of a material fact, or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; (3) obtains or attempts to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (4) engages or attempts to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.⁶⁸ Additionally, proposed Rule 9j–1(e) provided that the terms “purchase” and “sale” would have the same meaning as set forth in sections 3(a)(13) and (14) of the Exchange Act.⁶⁹

2. Commission Action

The Commission is adopting final Rule 9j–1(a), but has revised the rule to more closely follow the language used in the definitions of “purchase” and “sale,” and “buy” and “sell” in the Exchange Act, as amended by the Dodd-Frank Act, and to respond to commenter concerns.⁷⁰ Specifically, the rule makes it unlawful for any person, directly or indirectly, to effect any transaction in, or attempt to effect any transaction in, any security-based swap, or to purchase or sell, or induce or attempt to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security-based swap, as the context may require), in connection with which such person engages in the activities specified in Rules 9j–1(a)(1) through (6).⁷¹ Final Rule 9j–1(a) prohibits fraudulent, deceptive, or manipulative misconduct related to the payments, deliveries, rights, or obligations under a security-based swap if that misconduct occurs in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, a security-based swap.⁷² Further, the Commission is adopting Rule 9j–1(e) as

proposed but now renumbered as final Rule 9j–1(d).

Several commenters supported the application of Rule 9j–1(a) to the exercise of rights and performance of obligations under a security-based swap.⁷³ One commenter recognized that the proposed rule “appropriately recognizes that [security-based swaps] have unique characteristics in the form of ‘ongoing payments or deliveries between the parties throughout the life of the security-based swap pursuant to their rights and obligations,’ ” which creates additional opportunities for fraud and manipulation, as compared to other types of securities, therefore warranting “their own unique anti-fraud rule.”⁷⁴

Two commenters argued that the Commission exceeded its statutory authority by applying proposed Rule 9j–1(a) “to every interim performance obligation” and every exercise of a right under a security-based swap.⁷⁵ One commenter asserted that “[h]ad Congress intended” for Exchange Act section 9(j) to cover “actions related to the ongoing performance of obligations under a security-based swap agreement, it would have expressly done so in the Dodd-Frank Act or subsequent legislation, particularly given that it amended the definitions of ‘purchase’ and ‘sale’ to reflect security-based swaps.”⁷⁶ The commenter stated that “[i]n so doing, Congress made a determination to limit the covered actions to ‘execution,’ ‘termination,’ ‘exchange,’ or ‘extinguishing’ of rights or obligations under a security-based swap.”⁷⁷ The commenter also stated that “[t]here is also no precedent or support for the Commission to adopt a broad interpretation of the phrase ‘to effect any transaction in’ . . . as a basis for including interim performance obligations within the scope of proposed Rule 9j–1, as this has not been the traditional and longstanding

understanding of that statutory phrase.”⁷⁸ Another commenter asserted that the Commission could not use its prophylactic authority under section 9(j) as a means to “extend Proposed Rule 9j–1(a) beyond” what the commenter stated was “any natural reading of the terms ‘purchase’ or ‘sale.’ ”⁷⁹

The same two commenters also raised practical concerns about applying Rule 9j–1(a) to every exercise of a right or performance of an obligation under a security-based swap. One commenter stated that “if the proposed antifraud rule can be applied to any action or omission ‘related to performance of any obligation,’ market participants will undoubtedly seek to limit the scope of their transactions, and the terms of such transactions, in order to mitigate their exposure to liability under the rule” and some market participants would “terminate their involvement in the security-based swap market entirely.”⁸⁰ The commenter asserted that this result would “reduce liquidity in security-based swap markets and, by restricting hedging opportunities, have a material adverse effect on the availability and cost of capital for issuers.”⁸¹ The other commenter asserted that “Proposed Rule 9j–1(a)’s application to non-volitional conduct under [a security-based swap] would not be appropriate because it would cast uncertainty on a wide range of *bona fide* conduct necessary to the operation of the capital markets” and “risks chilling legitimate market conduct as market participants try to determine whether conduct unrelated to an affirmative investment decision could be judged after the fact to be prohibited.”⁸²

The Commission has carefully considered the comments and, as discussed below in sections II.A.2.a through II.A.2.c, is revising Rule 9j–1 to specify that it applies to misconduct that occurs in connection with effecting any transaction in, or attempting to effect any transaction in, any security-based swap, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security-based swap). The language in final Rule 9j–1(a) is based on section 9(j) of the

⁶⁸ See 2021 Proposing Release, 87 FR at 6703.

⁶⁹ See 15 U.S.C. 78c(a)(13) and (14).

⁷⁰ See 15 U.S.C. 78c(a)(13) and (14).

⁷¹ See *supra* sections II.B and II.C.

⁷² See final Rule 9j–1(a).

⁷³ See Letter from Andrew Park, Americans for Financial Reform Education Fund (“AFRED”), dated Mar. 21, 2022 (“AFRED Letter”); Letter from Stephen W. Hall and Jason Grimes, Better Markets, Inc., dated Mar. 21, 2022 (“Better Markets Letter”); Letter from Gina-Gail S. Fletcher, Duke University School of Law, dated Mar. 21, 2022 (“Fletcher Letter”).

⁷⁴ Better Markets Letter at 9. Another commenter also noted the “unique risks and long duration, with a potentially complex stream of payments and obligations” of security-based swaps in their support of the scope of the proposed rule. Fletcher Letter at 2.

⁷⁵ Letter from Jennifer W. Han, Managed Funds Association (“MFA”), dated Mar. 21, 2022 (“MFA Letter”), at 4. See *id.* at 3–8; IIB–ISDA–SIFMA Letter at 6–8.

⁷⁶ MFA Letter at 5. See IIB–ISDA–SIFMA Letter at 6.

⁷⁷ MFA Letter at 5.

⁷⁸ *Id.* at 7.

⁷⁹ IIB–ISDA–SIFMA Letter at 8.

⁸⁰ MFA Letter at 7–8 (emphasis in original).

⁸¹ MFA Letter at 8.

⁸² IIB–ISDA–SIFMA Letter at 8–9.

Exchange Act and the definitions of “purchase” and “sale,” and “buy” and “sell,” which were amended by the Dodd-Frank Act to take into account the unique characteristics of security-based swaps.⁸³ The final rule text also is revised to make it unlawful to “induce . . . the purchase or sale” of any security-based swap, in addition to “purchase or sell,” and “attempt to induce the purchase or sale of,” any security-based swap. This addition is made to track the statutory language of section 9(j) of the Exchange Act.⁸⁴ In addition to the changes to Rule 9j–1(a), in response to commenters’ practical concerns, as discussed in section II.E.2, the Commission is adopting affirmative defenses.

Depending on the facts and circumstances of a particular situation, as discussed in sections II.A.2.a through II.A.2.c below, final Rule 9j–1 may reach misconduct that affects the payments and deliveries that typically occur throughout the life of a security-based swap, if that misconduct occurs in connection with effecting or attempting to effect any transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap. Consistent with the operation of other antifraud provisions in the securities laws, whether that connection exists will be determined on a case-by-case basis.⁸⁵ Sections II.A.2.a through II.A.2.c below discuss the scope of “in connection with,” “purchases or sales,”

and “effecting transactions” in the context of final Rule 9j–1(a).

a. In Connection With

Final Rule 9j–1 prohibits misconduct “in connection with” effecting any transaction in, or attempting to effect any transaction in, any security-based swap, or when purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap. Even if taking an action related to payments and deliveries under any security-based swap would not itself constitute a purchase or sale, or effecting a transaction, conduct that affects payments and deliveries may occur “in connection with” purchases or sales, or effecting a transaction. The Supreme Court has “espoused a broad interpretation” of “in connection with,”⁸⁶ holding that the phrase “should be ‘construed not technically and restrictively, but flexibly to effectuate its remedial purposes.’”⁸⁷ Accordingly, the Court has held that “it is enough that the fraud alleged ‘coincide’ with a securities transaction.”⁸⁸ As one commenter who was critical of the breadth of proposed Rule 9j–1(a) acknowledged, “much of the illegitimate conduct described in the [proposing] release”—and in section I.B.2, *supra*—“involves a purchase or sale of securities.”⁸⁹

Moreover, the Supreme Court has held that the requirement that “deception occur ‘in connection with the purchase or sale of any security’” does not require “deception of an identifiable purchaser or seller” because “[t]he Exchange Act was enacted in part ‘to insure the maintenance of fair and honest markets’” generally.⁹⁰ The “in connection with” requirement accordingly can be satisfied “even though the person or entity defrauded is

not the other party to the trade”—or here, the counterparty to the relevant security-based swap.⁹¹ For that reason, misconduct that affects the payments and deliveries under one security-based swap could be prohibited by final Rule 9j–1 if that misconduct occurs in connection with effecting or attempting to effect transactions or purchasing or selling or attempting to induce the purchase or sale of any security-based swap, and not just the security-based swap that was the subject of the misconduct.

b. Purchases or Sales

Not only is “in connection with” construed broadly, Congress also has broadly defined what constitutes a “purchase” and “sale.” Generally, purchases and sales of securities include “contracts to buy, purchase or otherwise acquire” or “contracts to sell or otherwise dispose of” the security, respectively.⁹² For security-based swaps, as part of the provisions of the Dodd-Frank Act that gave the Commission new authority over that market, Congress added that purchases and sales also include “the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of rights or obligations under, a security-based swap, as the context may require.”⁹³ Final Rule 9j–1(a) accordingly prohibits fraudulent, deceptive, or manipulative conduct that affects ongoing payments and deliveries under a security-based swap if that misconduct occurs in connection with any activity that falls within those broad definitions.⁹⁴

⁹¹ *Id.* at 656.

⁹² 15 U.S.C. 78c(a)(13) and 78c(a)(14).

⁹³ 15 U.S.C. 77b(a)(18), 78c(a)(13), and 78c(a)(14).

⁹⁴ One commenter expressed concern that the term “terminate (other than on its scheduled maturity date)” in proposed Rule 9j–1(a) was “simultaneously too broad and too narrow.” Fletcher Letter at 2. The commenter stated that the term “would appear to exempt terminations at maturity from the scope of the rule” even if “an opportunistic scheme could be executed in line with the scheduled maturity date,” while applying to “contractually permitted terminations” prior to maturity that are “not conducted to intentionally distort the swap transaction.” *Id.* Consistent with Exchange Act sections 3(a)(13) and (14), the Commission has revised final Rule 9j–1(a) to state that a purchase or sale of a security-based swap includes, but is not limited to, a “termination (prior to its scheduled maturity date) . . . of . . . a security-based swap,” and includes any “similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security-based swap, as the context may require.” Depending on the context, the termination of a security-based swap on the scheduled maturity date could constitute such a “similar transfer or conveyance” or “extinguish[ment] of any rights or obligations.” And while a contractually permitted termination of

⁸³ The Dodd-Frank Act amended the definitions of “purchase” and “sale” in section 2(a)(18) of the Securities Act, 15 U.S.C. 77b(a)(18), the definitions of “buy” and “purchase” in section 3(a)(13) of the Exchange Act, 15 U.S.C. 78c(a)(13), and “sale” and “sell” in section 3(a)(14) of the Exchange Act, 15 U.S.C. 78c(a)(14), in the context of security-based swaps, to include “the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of rights or obligations under, a security-based swap, as the context may require.” Final Rule 9j–1(d) makes clear that “[f]or purposes of this section, the terms ‘purchase’ and ‘sale’ shall have the same meanings as set forth in Sections 3(a)(13) (15 U.S.C. 78c(a)(13)) and 3(a)(14) (15 U.S.C. 78c(a)(14)) of the Act.”

⁸⁴ See 15 U.S.C. 78i(j).

⁸⁵ One commenter asserted that the Commission’s rulemaking authority under section 9(j) is limited to “identifying specific transactions, acts, practices and courses of business” that are fraudulent, deceptive, or manipulative. IIB–ISDA–SIFMA Letter at 8. The text of section 9(j), which authorizes the Commission to “define, and prescribe means reasonably designed to prevent, such transactions, acts, practices, and courses of business as are fraudulent, deceptive, or manipulative,” does not require the Commission to identify “specific transactions, acts, practices and courses of business.” Because security-based swaps are complex, and related strategies are constantly evolving, new opportunities for misconduct likewise constantly arise. Rule 9j–1 must be flexible to enable the Commission to prevent such misconduct.

⁸⁶ *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 85 (2006).

⁸⁷ *SEC v. Zandford*, 535 U.S. 813, 819 (2002) (citations omitted).

⁸⁸ *Dabit*, 547 U.S. at 85 (citation omitted). See *Superintendent of Ins. of State of N.Y. v. Bankers Life & Cas. Co.*, 404 U.S. 6, 12 (1971) (“deceptive practices touching [a] sale” are actionable); *Chadbourne & Parke LLP v. Troice*, 571 U.S. 377, 387 (2014) (fraud occurred “in connection with” a purchase or sale if it was “material to and ‘coincided with’ third-party securities transactions” (quoting *Dabit*, 547 U.S. at 85)).

⁸⁹ IIB–ISDA–SIFMA Letter at 9. As an example, the commenter stated, “the credit event under a credit default swap . . . typically settles through an auction process that involves purchases and sales of securities [and] many of the transactions with reference entities identified by the Commission are securities transactions.” *Id.* As discussed below, see *infra* section II.A.2.c, settlement also is part of effecting a securities transaction. See 15 U.S.C. 78bb(e)(3)(C).

⁹⁰ *United States v. O’Hagan*, 521 U.S. 642, 657–58 (1997) (quoting 15 U.S.C. 78b).

Those definitions are not limited to executions, terminations, assignments, exchanges, or similar transfer or conveyance of, or extinguishing of *all* the rights or obligations under, a security-based swap. Therefore, the Commission also has revised final Rule 9j-1(a) to add the words “including but not limited to, in whole or in part” before listing the activities enumerated in Exchange Act sections 3(a)(13) and (14).⁹⁵ In addition, the final rule includes the word “any” before “rights or obligations.” These modifications clarify that, for purposes of the antifraud and anti-manipulation provisions of paragraph (a), the definitions of purchase and sale encompass, among other things, *partial* executions, terminations, assignments, exchanges, transfers or conveyances of, or extinguishing of *any* rights or obligations under, a security-based swap, as the context may require.⁹⁶ The Commission stated in the 2021 Proposing Release that the Exchange Act’s definitions of purchase and sale in the context of security-based swaps “incorporate actions that have an impact on some, but not all, rights and obligations” under a security-based swap, including “partial executions, terminations, assignments, exchanges, transfers, or extinguishments of rights or obligations.”⁹⁷ Commenters did not disagree.⁹⁸

It also is reasonable to include partial executions, terminations, assignments, exchanges, or similar transfers or conveyances of, or extinguishing of rights or obligations under, a security-based swap within the scope of the rule because those actions could result in amendments to the material terms of the security-based swap and, therefore, result in a new security-based swap

a security-based swap prior to maturity constitutes a purchase or sale under the terms of both section 3(a) and Rule 9j-1(a), Rule 9j-1(a) prohibits only fraudulent, deceptive, or manipulative conduct in connection with a termination.

⁹⁵ The phrase “but not limited to” reflects the fact that Exchange Act sections 3(a)(13) and (14) do not limit the definition of purchase or sale to the enumerated activities, contrary to the assertion of one commenter. See MFA Letter at 5; *supra* notes 76 and 77, and related discussion.

⁹⁶ See Rule 9j-1(a) (“to purchase or sell, or induce or attempt to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security based-swap, as the context may require”).

⁹⁷ 2021 Proposing Release, 87 FR at 6661.

⁹⁸ See, e.g., IIB-ISDA-SIFMA Letter at 7 (“We concur with this reading, insofar as it would extend Proposed Rule 9j-1(a) to an affirmative action relating to an investment decision and affecting a material term of [a security-based swap], for example a partial termination or assignment.”).

(that is, a “purchase” or “sale”).⁹⁹ Security-based swaps take many different forms and are used for many different purposes, but often are used to hedge risks. Even a partial change in any of the rights and obligations underlying the security-based swap—particularly those related to ongoing payments and deliveries—could affect the alignment of that hedge with the attendant risk and, under a facts and circumstances analysis, could constitute a purchase or sale of a security-based swap. A different approach—one that only prohibited misconduct in connection with the extinguishment of all of the rights and obligations under a security-based swap—would leave market participants vulnerable to the risks that the security-based swap was entered into to address (as well as decrease the alignment of any hedge entered into to address the risk of the security-based swap itself). These revisions to the text of final Rule 9j-1 also ensure that market participants cannot evade liability under Rule 9j-1 by, for example, structuring fraudulent, deceptive, or manipulative conduct so that some portion of a counterparty’s rights and obligations under a security-based swap remain in place.

Relatedly, the Commission reiterates that “[i]f the material terms of a” security-based swap “are amended or modified during its life based on an exercise of discretion and not through predetermined criteria or a predetermined self-executing formula,” then “the amended or modified” security-based swap is a “new” security-based swap.¹⁰⁰ For example,

⁹⁹ See *infra* note 100, and related discussion of amendments of material terms.

¹⁰⁰ Product Definitions Release, 77 FR at 48286; see 17 CFR 230.145(a) Preliminary Note (“Changing the nature and terms of an investor’s relationship to the issuer may represent the offer or sale of a new security for value.”); 2021 Proposing Release, 87 FR at 6661. Similarly, courts have found that if an amendment or modification to the terms of a security results in “a significant change in the nature of the investment or risk” related to that security, a new security results. *Department of Economic Development v. Arthur Anderson & Co. (U.S.A.)*, 924 F. Supp. 449, 478 (S.D.N.Y. 1996) (citation omitted). See also, e.g., *Ingenito v. Bermac Corp.*, 376 F. Supp. 1154, 1181 (S.D.N.Y. 1974) (considering claims of Section 10(b) and finding that “a purchase or a sale arises when the nature and terms of an investor’s involvement in a business enterprise are substantially altered by the creation of new rights or obligations”); Louis Loss, et al., Securities Regulation § 3.A.2 (2023) (citing to *N. Natural Gas Co.*, 14 SEC 506, 509 (1943) (noting that “for example, a change in interest or dividend rate or a liquidation preference or underlying security, or a change in the identity of the issuer, would seem clearly to result in a new security”)). Changes are more likely to be considered “significant” if they are adverse to the security holders affected. See, e.g., *SEC v. Associated Gas & Electric Co.*, 99 F.2d 795, 797–98 (2nd Cir. 1938) (holding that under the Public Utility Holding

contrary to one commenter’s assertion,¹⁰¹ amendments to terms regarding ongoing rights and obligations under a security-based swap, including those related to ongoing payments and deliveries, could result in a new transaction.¹⁰² When an amendment or modification constitutes a purchase or sale of a security-based swap, Rule 9j-1(a) prohibits any fraudulent, deceptive, or manipulative conduct that occurs in connection with it.

Two commenters agreed that “Rule 9j-1 should be applicable . . . if the parties to a security-based swap transaction make changes to material terms that result in the creation of a new transaction.”¹⁰³ But these commenters disagreed with the Commission’s assertion in the 2021 Proposing Release that such a modification or amendment—and thus a purchase or sale—occurs when a party engages in conduct that “has a material impact on any payment or delivery under the security-based swap, such that it would not be consistent with what a reasonable person would have expected to pay, deliver, or receive absent such conduct.”¹⁰⁴ Under final Rule 9j-1(a), whether a purchase or sale of a security-based swap has occurred will depend on the facts and circumstances and therefore the operation of the rule, as revised, is not dependent on the language in the 2021 Proposing Release

Company Act of 1935, the extension of the maturity date of a debt security increased the risk to the holder and therefore constituted the sale of a new security). See also *Rathborne v. Rathborne*, 683 F.2d 914, 920 (5th Cir. 1982) (“In determining whether a party to a securities transaction is a ‘purchaser’ or ‘seller,’ we must ask whether the transaction has wrought a fundamental change in the nature of the plaintiff’s investment [T]he core issue is whether the transaction has transformed the plaintiff into the functional equivalent of a purchaser or seller—has the plaintiff been forced to exchange his stock for shares representing a participation in a substantially different enterprise? We must focus upon the economic reality of the transaction, and determine whether the transaction has ‘transformed’ the plaintiff’s interests ‘in any real sense.’” (citations omitted)); *Keys v. Wolfe*, 709 F.2d 413, 417 (5th Cir. 1983) (holding that “the determination of whether” there has been “a significant change in the nature of the investment or in the investment risks . . . hinges on the economic reality of the transaction rather than on formal changes in the rights and obligations of the parties”).

¹⁰¹ MFA Letter at 6.

¹⁰² See Loss, *supra* note 100 (noting that “a change in interest or dividend rate”—which is an ongoing right or obligation—“would seem clearly to result in a new security”).

¹⁰³ MFA Letter at 4. See IIB-ISDA-SIFMA Letter at 7 (“[M]arket participants have arranged their affairs to treat such an exercise of discretion to amend a material term of [a security-based swap] as tantamount to the ‘purchase’ or ‘sale’ of [a security-based swap], including for anti-fraud purposes.”).

¹⁰⁴ 2021 Proposing Release, 87 FR at 6661. See IIB-ISDA-SIFMA Letter at 7–8; MFA Letter at 4.

quoted by the commenters.¹⁰⁵ Applying a facts and circumstances analysis, if conduct that affects ongoing payments or deliveries results in the extinguishment of a right or obligation under a security-based swap, such as the right to such a payment or delivery, or otherwise results in a new transaction, then a purchase or sale will have occurred, and any related fraudulent, deceptive, or manipulative misconduct will fall within Rule 9j–1’s prohibitions.

c. Effecting Transactions

Exchange Act section 9(j), and accordingly final Rule 9j–1(a), also is not limited to prohibitions on fraud, manipulation, or deception in connection with the purchase or sale of a security-based swap, but also encompasses misconduct in connection with effecting a transaction in any security-based swap. While the term “transaction” “is not defined in the Act, its broad meaning in everyday usage” and “the context in which it is used in the various sections of the Act” demonstrate that “it has a broader meaning than purchases or sales.”¹⁰⁶ The Commission accordingly has construed the term “to effect any transaction in” a security, variations of which appear in numerous provisions of the securities laws, to include activity such as placing bids or orders, and clearance and settlement of a securities transaction.¹⁰⁷ The Commission also has

stated that “key aspects of the overall process of effecting security-based swap transactions” include “sales, booking and cash and collateral management activities.”¹⁰⁸

Final Rule 9j–1(a) therefore prohibits fraudulent, manipulative, or deceptive conduct related to the exercise of rights or performance of obligations—including ongoing payments and deliveries—under a security-based swap if that misconduct occurs in connection with a broad range of activities “beyond the actual consummation of purchases or sales.”¹⁰⁹ For example, as discussed in section II.C below, a manipulation of the ongoing payments and deliveries under a security-based swap could be used to “affect[] the market artificially by raising or depressing securities prices,” and that conduct would be connected to effecting transactions in security-based swaps.¹¹⁰ Similarly, as one commenter noted, a “misappropriation of customer margin”

would be connected to effecting a security-based swap transaction.¹¹¹

In addition, the Commission is extending the application of final Rule 9j–1(a) to fraudulent, deceptive, or manipulative misconduct that occurs in connection with an “attempt” to effect a transaction in any security-based swap. This application is consistent with section 9(j)’s prohibition of fraud, deception, and manipulation in connection with an “attempt to induce the purchase or sale of” any security-based swap and is supported by case law that recognizes that fraudulent, deceptive, or manipulative conduct need not be successful to violate the securities laws.¹¹² It is also a “means reasonably designed to prevent” misconduct that results in completed transactions, which the statute explicitly prohibits.¹¹³

B. Fraudulent, Manipulative, or Deceptive Conduct

1. Proposed Approach

Proposed Rules 9j–1(a)(1) through (4), describing the prohibited fraudulent, manipulative, or deceptive conduct, was structured to include the antifraud and anti-manipulation provisions—in section 10(b) of the Exchange Act, and Rule 10b–5 thereunder, and section 17(a) of the Securities Act—that apply to *all* securities (including security-based swaps), and the additional antifraud and anti-manipulative authority specific to security-based swaps provided to the Commission in section 9(j) of the Exchange Act. Specifically, the proposed rule would have prohibited: (1) employing or attempting to employ any device, scheme, or artifice to defraud or manipulate; (2) making or attempting to make any untrue statement of a material fact, or omitting to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were

¹⁰⁵ See *supra* note 96. The language “as the context may require,” which is included in Rule 9j–1, comes from the definitions of purchase and sale in Exchange Act sections 3(a)(13) and 3(a)(14), and recognizes the need to consider the facts of a particular situation to determine whether a purchase or sale has occurred.

¹⁰⁶ *In re Kidder Peabody & Co.*, 18 S.E.C. 559, 1945 WL 332559, at *8 (Apr. 2, 1945) (interpreting Exchange Act section 9(a)(2) and finding that Congress intended to extend its “prohibition against manipulation . . . beyond the actual consummation of purchases or sales,” to include “affecting the market artificially by raising or depressing security prices, or creating actual or apparent activity, whether or not accomplished by actual purchases or sales”). See *SEC v. Lek Sec. Corp.*, 276 F. Supp. 3d 49, 62 (S.D.N.Y. 2017) (“Courts have held that a ‘series of transactions’ includes not only completed purchases or sales but also bids and orders to purchase or sell securities.”).

¹⁰⁷ *Kidder Peabody*, 1945 WL 332559, at *8. See 15 U.S.C. 78bb (identifying “clearance, settlement, and custody” as “functions incidental” to “effect[ing] securities transactions”). Settlement of security-based swaps occurs over time in accordance with contractually agreed upon terms (in contrast to other securities such as debt or equity, where settlement occurs when the parties exchange securities for cash equal to the full value of the securities sold). See T+1 Adopting Release, 88 FR at 13878, 13883 (quoting SIFMA who noted that, that for security-based swaps, settlement occurs when a “final net payment is paid by one party to the other at a future point in time to which the parties have contractually agreed” (citation omitted)). See also *supra* note 32.

¹⁰⁸ Registration Process for Security-Based Swap Dealers and Major Security-Based Swap Participants, Exchange Act Release No. 75611 (Aug. 5, 2015), 80 FR 48964, 48976 n.99 (Aug. 14, 2015) (“SBS/MSBSP Registration Process Release”). In the SBS/MSBSP Registration Process Release, in the context of determining who has to register as a security-based swap dealer, the Commission identified some activities that would fall within the definition of “involved in effecting security-based swap transactions”—for example, pricing security-based swap positions and managing collateral. The identification of these activities as part of “the overall process of effecting” a transaction “also serves to demonstrate that not all activities in that process take place prior to the execution of the security-based swap. See MFA Letter at 7 (asserting “[i]nterpretations of ‘effect[ing] a transaction,’ . . . have been limited to the process leading to the purchase or sale of a security” (emphasis added)). In addition, as the Commission has previously explained in the context of broker-dealers, “effecting” transactions in securities has been construed broadly to encompass a wide range of activities, including: (1) transmission of an order for execution, order execution, clearance and settlement, and arranging for the performance of any such function, see 17 CFR 240.11a2–2(T); 2014 Temp Rule 11a2–2(T); and (2) screening potential transaction participants for creditworthiness, soliciting securities transactions, routing or matching orders or facilitating the execution of a transaction, handling customer funds and securities, and preparing and sending transaction confirmations, Definition of Terms in and Specific Exemptions for Banks, Savings Associations, and Savings Banks Under Sections 3(a)(4) and 3(a)(5) of the Securities Exchange Act of 1934, Exchange Act Release No. 44291 (May 11, 2001), 66 FR 27760, 27772–73 (May 18, 2001)). Critically, several of these activities are not limited to pre-trade actions (e.g., clearance, settlement, and handling counterparty funds).

¹⁰⁹ *Kidder Peabody*, 1945 WL 332559, at *8. See 15 U.S.C. 78bb (identifying “clearance, settlement, and custody” as “functions incidental” to “effect[ing] securities transactions”).

¹¹⁰ *Id.* For example, a platform that effects transactions in security-based swaps, such as binary options or other event contracts, could fraudulently extinguish a holder’s right to payment. Such conduct could also affect the market price for similar binary options or event contracts.

¹¹¹ IIB–ISDA–SIFMA Letter at 9.

¹¹² See, e.g., *Koch v. SEC*, 793 F.3d 147, 153–54 (D.C. Cir. 2015) (“[I]ntent—not success—is all that must accompany manipulative conduct to prove a violation of the Exchange Act and its implementing regulations.” (citation omitted)); *Kuehnert v. Texstar Corp.*, 412 F.2d 700, 704 (5th Cir. 1969) (“[W]e are not convinced of any difference in substance between a successful fraud and an attempt. The statutory phrase ‘any manipulative or deceptive device,’ 15 U.S.C. 78j(b), seems broad enough to encompass conduct irrespective of its outcome.”); *Lek*, 276 F. Supp. at 60 (S.D.N.Y. 2017) (“manipulative conduct need [not] be successful in order to violate the securities laws”); *SEC v. Martino*, 255 F. Supp. 2d 268, 287 (S.D.N.Y. 2003) (“an attempted manipulation is as actionable as a successful one”). See also *Lorenzo v. SEC*, 139 S. Ct. 1094, 1104 (2019) (“The Commission . . . need not show reliance in its enforcement actions.”).

¹¹³ 15 U.S.C. 78i(j).

made, not misleading; (3) obtaining or attempting to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (4) engaging or attempting to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.¹¹⁴

Proposed Rules 9j–1(a)(1) and (2), consistent with section 10(b) of the Exchange Act, and Rule 10b–5 thereunder, and section 17(a)(1) of the Securities Act, would have required scienter. In contrast, proposed Rules 9j–1(a)(3) and (4) would not have required scienter and would have extended to conduct that is at least negligent, consistent with sections 17(a)(2) and (3) of the Securities Act.

2. Commission Action

After considering the comments, the Commission is revising proposed Rule 9j–1(a) as discussed below in sections II.B.2.a and II.B.2.b.¹¹⁵

Final Rule 9j–1(a)(1) is being adopted as proposed, and will prohibit employing or attempting to employ any device, scheme, or artifice to defraud or manipulate. Although most of that language is derived from section 10(b) of the Exchange Act,¹¹⁶ Rule 10b–5 thereunder,¹¹⁷ and section 17(a)(1) of the Securities Act,¹¹⁸ the inclusion of

“manipulate” also comes from the text of section 9(j)).

Final Rule 9j–1(a)(2), which is based on section 9(j) and Rule 10b–5, will prohibit making or attempting to make any untrue statement of a material fact, or omitting to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

Proposed paragraphs (a)(3) and (4) are revised to separate attempted conduct into a new paragraph (a)(5) (to which a scienter standard is applicable, as discussed in section II.B.2.b below). Paragraph (a)(3) will prohibit obtaining money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Paragraph (a)(4) will prohibit engaging in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person. Paragraphs (a)(3) and (4) are based on sections 17(a)(2) and (3) of the Securities Act, as well as Exchange Act section 9(j), which similarly prohibits “engag[ing] in any transaction, practice, or course of business which operates as a fraud or deceit upon any person.”¹¹⁹

Paragraph (a)(5) will prohibit attempting to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading or attempts to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person. As discussed in section II.B.2.b below, the prohibition on attempted conduct in paragraphs (a)(1), (a)(2), and (a)(5) is premised on the text of section 9(j), including the Commission’s prophylactic authority to “prescribe means reasonably designed to prevent, such transactions, acts, practices, and courses of business as are fraudulent, deceptive, or manipulative, and such quotations as are fictitious.”

The provisions described above generally prohibit a range of fraudulent, manipulative, and deceptive conduct in the security-based swap market.¹²⁰ Case law related to section 10(b) of the Exchange Act, Rule 10b–5 thereunder,

and section 17(a) of the Securities Act provides guidance as to what conduct violates section 9(j) of the Exchange Act and Rule 9j–1 thereunder.

a. Scienter and Negligence Standards

Findings of misconduct under final Rules 9j–1(a)(1) and (2) require scienter while final Rules 9j–1(a)(3) and (4) do not require scienter and extend to conduct that is at least negligent.¹²¹ While both Rules 9j–1(a)(2) and (3) prohibit material misstatements and omissions,¹²² they address different levels of culpability.¹²³ Specifically, Rule 9j–1(a)(2) will apply when there is evidence of scienter (e.g., when a party to a security-based swap knowingly or recklessly makes a false statement even though the party may not receive any money or property as a result). In contrast, Rule 9j–1(a)(3) extends to conduct that is at least negligent (e.g., when a party to a security-based swap knows or reasonably should know that a statement was false or misleading and directly or indirectly obtains money or property by means of such statement).

Several commenters argued for a scienter standard, rather than the proposed negligence standard, with respect to paragraphs (3) and (4) of Rule 9j–1(a).¹²⁴ Specifically, one commenter

¹²¹ In addition, findings of misconduct under paragraphs (a)(5) and (a)(6) will require scienter. See *infra* section II.B.2.b (paragraph (a)(5)) and section II.C.2 (paragraph (a)(6)).

¹²² Consistent with section 10(b) of the Exchange Act, such misstatements and omissions must be material to be actionable. “The question of materiality, it is universally agreed, is an objective one, involving the significance of an omitted or misrepresented fact to a reasonable investor . . . there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 445, 449 (1976). See also *Basic v. Levinson*, 485 U.S. 224, 233 (1988).

¹²³ In addition to differences in the standard, there are additional deviations between Rules 9j–1(a)(2) and (3), notwithstanding the significant overlap in the rule text. For example, while paragraph (a)(2), like Rule 10b–5(b), makes it unlawful to make any untrue statement of a material fact, paragraph (a)(3), like section 17(a)(2) of the Securities Act does not use the word “make.” Based on that difference courts have contrasted the application of Rule 10b–5(b) from the application of section 17(a)(2) of the Securities Act as it relates to determining who is the maker of a material misstatement. See, e.g., *SEC v. Big Apple Consulting USA, Inc.*, 783 F.3d 786, 797 (11th Cir. 2015) (“[W]e . . . agree with the Securities and Exchange Commission’s recent opinion, which held ‘Janus’s limitation on primary liability under Rule 10b–5(b) does not apply to claims arising under Section 17(a)(2).’”); *SEC v. Tambone*, 597 F.3d 436, 444 (1st Cir. 2010) (en banc) (contrasting the language of Rule 10b–5(b) with “the expansive language of section 17(a)(2),” which covers “the ‘use’ of an untrue statement of material fact (regardless of who created or composed the statement)”).

¹²⁴ See IIB–ISDA–SIFMA Letter at 13 (arguing against applying a negligence standard for

¹¹⁴ 2021 Proposing Release, 87 FR at 6658–60.

¹¹⁵ Final Rule 9j–1(a)(6), which is a revision of proposed Rule 9j–1(b), is discussed in section II.C below.

¹¹⁶ Section 10(b) of the Exchange Act provides that “[i]t shall be unlawful for any person, directly or indirectly . . . (b) to use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.” 15 U.S.C. 78j(b).

¹¹⁷ Rule 10b–5 under the Exchange Act provides that “[i]t shall be unlawful for any person, directly or indirectly . . . (a) to employ any device, scheme, or artifice to defraud, (b) to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading, or (c) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.” 17 CFR 240.10b–5.

¹¹⁸ Section 17(a) of the Securities Act provides that “[i]t shall be unlawful for any person in the offer or sale of securities . . . directly or indirectly—(1) to employ any device, scheme, or artifice to defraud, or (2) to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading, or (3) to engage in any

transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser.” 15 U.S.C. 77q(a).

¹¹⁹ See *supra* notes 5 and 118.

¹²⁰ See 2021 Proposing Release, 87 FR at 6659.

argued that applying a negligence standard “is inconsistent with the concept of fraud” and that “mere human error—which often occurs from the high volume of the [security-based swaps] business/frequent settlement activities—could result in liability.”¹²⁵ Another commenter stated that, at a minimum, “any liability for interim actions taken during the term of the security-based swap should be subject to a scienter standard.”¹²⁶ In addition, other commenters believed that a negligence based standard would be “disruptive to” or “chill” the security-based swap market¹²⁷ and interfere with the legitimate actions taken by lenders engaged in security-based swap transactions.¹²⁸

Although the Commission has considered the concerns raised by these commenters, it is adopting Rules 9j–

attempted conduct); LSTA Letter, at 5–7; MFA Letter at 12; Letter from John R. Williams, Milbank LLP, dated Mar. 22, 2022 (“Milbank Letter”), at 5. The European Banking Federation (“EBF”) supports the arguments in the IIB-ISDA–SIFMA Letter regarding proposed Rule 9j–1. See Letter from EBF, dated Apr. 1, 2022, at 1. As proposed, paragraphs (3) and (4) of Rule 9j–1(a) would have prohibited actions related to security-based swaps in which a person obtains or attempts to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or in which a person engages or attempts to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

¹²⁵ See Milbank Letter at 5.

¹²⁶ MFA Letter at 12–13 (arguing that liability under Rule 9j–1(a)(3) and (4) should be subject to scienter because security-based swap transactions are between “sophisticated counterparties dealing directly with each other on negotiated terms” rather than “impersonal transactions” where there is a stronger argument for imposing liability under section 17(a) without scienter because it is harder to form a specific intent absent a relationship between the purchaser and the seller). Actions by the Commission demonstrate that security-based swap transactions are not always between sophisticated counterparties with ongoing relationships. See, e.g., *In the Matter of Plutus Financial Inc. d/b/a Abra and Plutus Technologies Philippines Corp.*, Exchange Act Release No. 89296 (July 13, 2020) (offering security-based swaps to retail investors via a phone application); *In the Matter of Forcerank LLC*, Exchange Act Release No. 79093 (Oct. 13, 2016) (illegally offering complex security-based swaps to retail investors). See also SEC Binary Options Fraud Alert, *supra* note 63 (alerting investors of fraudulent binary options internet-based trading platforms).

¹²⁷ See, e.g., MFA Letter at 12; Milbank Letter at 5. See also ACLI Letter at 6 (arguing that “a negligence standard . . . could impact detrimentally other market participants that are involved in private credit markets and originations”).

¹²⁸ See LSTA Letter at 5–6 (supporting a scienter standard to “address the concern that a lender could be subject to negligence claims as a result of the often-fluid nature of security-based swap or loan transactions that may be subject to private negotiations, restructuring, or amendment at any given time”).

1(a)(1) through (4) using the same standards as proposed, with the exception of the attempted misconduct addressed in paragraph (a)(5), as discussed below. Each of these four provisions is based on an existing statutory and regulatory provision that is supported by a large body of case law. Final Rules 9j–1(a)(1) and (2), consistent with section 10(b) of the Exchange Act, and Rule 10b–5 thereunder,¹²⁹ and section 17(a)(1) of the Securities Act,¹³⁰ require scienter. In contrast, final Rules 9j–1(a)(3) and (4) do not require scienter and extend to conduct that is at least negligent, consistent with sections 17(a)(2) and (3) of the Securities Act.¹³¹

¹²⁹ To state a claim under section 10(b) of the Exchange Act, and Rule 10b–5 thereunder, the Commission must establish that the misstatements or omissions were made with scienter. See, e.g., *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976). The Supreme Court has defined scienter as “a mental state embracing intent to deceive, manipulate or defraud.” *Id.* Recklessness will generally satisfy the scienter requirement. See, e.g., *Sunstrand Corp. v. Sun Chemical Corp.*, 553 F.2d 1033, 1045 (7th Cir. 1977). See also *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 198 (1st Cir. 1999); *SEC v. Environmental, Inc.*, 155 F.3d 107, 111 (2d Cir. 1998).

¹³⁰ Establishing violations of Securities Act section 17(a)(1) requires a showing of scienter. See, e.g., *Aaron v. SEC*, 446 U.S. 680, 701–02 (1980). Scienter is the “mental state embracing intent to deceive, manipulate or defraud.” *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976). See also section 206(1) of the Investment Advisers Act of 1940 (“Advisers Act”), which makes it unlawful for an investment adviser to employ any device, scheme, or artifice to defraud any client or prospective client. 15 U.S.C. 80b–6(1). Claims arising under section 206(1) of the Advisers Act require scienter. See, e.g., *Robare Grp. LTD v. SEC*, 922 F.3d 468, 472 (D.C. Cir. 2019); *SEC v. Moran*, 922 F. Supp. 867, 896 (S.D.N.Y. 1996); *Carroll v. Bear, Stearns & Co.*, 416 F. Supp. 998, 1001 (S.D.N.Y. 1976).

¹³¹ Actions pursuant to sections 17(a)(2) and 17(a)(3) of the Securities Act do not require a showing of scienter. See, e.g., *Aaron*, 446 U.S. at 701–02. In *Aaron*, the Supreme Court sought to determine whether scienter was required in a Commission injunctive proceeding pursuant to the antifraud provisions of section 10(b) of the Exchange Act and section 17(a) of the Securities Act. The Court examined the language of both sections and determined that scienter was required under section 10(b) because the words “manipulative,” “device,” and “contrivance,” which are used in the statute, evidenced a Congressional intent to proscribe only knowing or intentional misconduct. Similarly, the Court concluded that subsection (1) of section 17(a) required proof of scienter because Congress used such words as “device,” “scheme,” and “artifice to defraud.” *Aaron*, 446 U.S. at 696. In contrast, the Court concluded that the absence of such words under subsections (2) and (3) of section 17(a) demonstrated that no scienter was required. Section 17(a)(2) prohibits any person from obtaining money or property “by means of any untrue statement of a material fact or omission to state a material fact,” which the Court found to be “devoid of any suggestion whatsoever of a scienter requirement.” *Aaron*, 446 U.S. at 696. Similarly, the Court found, in construing section 17(a)(3), under which it is unlawful for any person “to engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit,” that

Although, as noted above, certain commenters argued that a negligence standard would be inconsistent with a fraud rule,¹³² the Supreme Court has determined that a negligence standard applies to the fraud rule upon which the provisions in Rules 9j–1(a)(3) and (4) are based—Securities Act sections 17(a)(2) and (3).¹³³ In *Aaron v. SEC*, the Supreme Court stated that violations of these provisions could be satisfied by a finding of a mental state lower than scienter.¹³⁴ Specifically, the Court determined that the “language of [section] 17 (a)(2), which prohibits any person from obtaining money or property ‘by means of any untrue statement of a material fact or any omission to state a material fact,’ is devoid of any suggestion whatsoever of a scienter requirement”¹³⁵ and “the language of [section] 17 (a)(3), under which it is unlawful for any person ‘to engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit,’ (emphasis added) quite plainly focuses upon the effect of particular conduct on members of the investing public, rather

scienter was not required because it “quite plainly focuses upon the effect of particular conduct on members of the investing public, rather than upon the culpability of the person responsible.” *Aaron*, 446 U.S. at 697.

¹³² See MFA Letter at 12 (arguing that a negligence standard could extend liability “to conduct that is merely negligent or inadvertent, without requiring any intent by the party to mislead or defraud”); Milbank Letter at 5 (arguing in addition that the negligence standard is inconsistent with the concept of fraud which requires intent or recklessness and that human error could result in liability). Courts have found, for example, that the negligence standard in 17(a) requires a defendant to act in the manner that a reasonably prudent person in its position would have acted under the circumstances. *SEC v. Shanahan*, 646 F.3d 536, 545–46 (8th Cir. 2011).

¹³³ Moreover, these provisions are consistent with the antifraud and anti-manipulation authority that the Commission had under the Commodity Futures Modernization Act over security-based swap agreements as then defined in section 206B of the Gramm-Leach-Bliley Act. Commodity Futures Modernization Act of 2000, Public Law 106–554, section 1(a)(5), 114 Stat. 2763 (Dec. 21, 2000) (codified at 15 U.S.C. 78j(b)). Prior to the passage of the Dodd-Frank Act, section 206B of the Gramm-Leach-Bliley Act defined a “security-based swap agreement” as a “swap agreement . . . of which a material term is based on the price, yield, value, or volatility of any security or any group or index of securities, or any interest therein.” Gramm-Leach-Bliley Act, Public Law 106–102 section 206B, 113 Stat 1338 (Nov. 12, 1999) (set out as a note under 15 U.S.C. 78(c). Given that many security-based swaps would have been security-based swap agreements before the passage of the Dodd-Frank Act, it is contrary to the purposes of the Dodd-Frank Act to create a scienter standard under Rule 9j–1 for actions that would have been covered by a negligence standard under section 17(a) of the Securities Act pre-Dodd-Frank.

¹³⁴ See *Aaron*, 446 U.S. at 696–97 (discussing the standard under sections 17(a)(2) and (3) of the Securities Act).

¹³⁵ *Id.* at 696.

than upon the culpability of the person responsible.”¹³⁶ It would be incongruous to provide different standards in Rules 9j–1(a)(3) and (4), which use language identical to the language in sections 17(a)(2) and (3) of the Securities Act that was interpreted by the Supreme Court.

In addition, the Commission disagrees with commenters who argued that scienter must apply because of the ongoing and “fluid nature” of security-based swap transactions.¹³⁷ The Commission agrees, as stated previously, that a fundamental aspect of a security-based swap is the ongoing payments or deliveries between the parties through the life of the security-based swap. That characteristic creates additional opportunities for misconduct after the parties enter into the security-based swap contract and during the term of the security-based swap.¹³⁸ The Commission disagrees, however, that the nature of security-based swaps—and the additional opportunities for harm—warrants applying a scienter standard rather than following the precedent applicable to sections 17(a)(2) and (3) of the Securities Act. Following the Court’s ruling in *Aaron v. SEC*, Rules 9j–1(a)(3) and (4) focus on the “effect” of the particular misconduct, and therefore, a negligence standard is appropriate.

Similarly, the Commission does not agree with the commenters who suggested that the sophistication of, or the extent of the relationship between, counterparties to a security-based swap negates the need to prohibit certain misconduct, such as the acquisition of money or property by means of an untrue statement or acts that operate as a fraud, absent a showing of scienter, as provided in Rules 9j–1(a)(3) and (4).¹³⁹ Although the courts and Commission have, for example, recognized that certain investors, based on qualities

such as wealth or asset size,¹⁴⁰ do not always need the same disclosure and similar investor protections as retail investors because they can “fend for themselves,”¹⁴¹ the Commission and courts have also stated that sophisticated investors are entitled to protections of the general antifraud or anti-manipulation provisions of the Federal securities laws.¹⁴² Nothing in section 9(j) suggests that it should only apply to a limited subset of market participants.

To the extent that there is overlap between Rules 9j–1(a)(3) and (4) and sections 17(a)(2) and (3) of the Securities Act, introducing a different standard would be counter to the position the Supreme Court took with regard to identical language used in section 17(a) of the Securities Act.¹⁴³ A different standard could also potentially undermine the effectiveness of both provisions in certain circumstances, such as when the case law applicable to one provision contradicts the other in a way that cannot be rationalized by the differences in the underlying instruments.

Commenters also argued that the negligence standard of Rules 9j–1(a)(3) and (4) would chill or disrupt the security-based swap market and would capture actions, including errors, taken in connection with normal and legitimate business activity due to the nature of security-based swap transactions.¹⁴⁴ However, as discussed,

courts have recognized that sections 17(a)(2) and (3) of the Securities Act, on which Rules 9j–1(a)(3) and (4) are based, focus on the person’s conduct and the effect of that conduct, rather than the “culpability of the persons responsible.”¹⁴⁵ Like Securities Act sections 17(a)(2) and (3), final Rules 9j–1(a)(3) and (4) will not capture normal and legitimate business activity. Courts have found, for example, that the negligence standard requires that to be deemed in violation of these provisions, a defendant must act in a manner contrary to the manner in which a reasonably prudent person in the defendant’s position would have acted under the circumstances.¹⁴⁶ Accordingly, a violation of Rules 9j–1(a)(3) and (4) would require more than a mere mistake.¹⁴⁷

b. Attempted Conduct

Finally, as proposed, the Rule 9j–1(a) prohibitions would have extended to the attempted fraudulent, manipulative or deceptive conduct described in paragraphs (a)(1) through (4) of the rule. The Commission largely adopts Rule 9j–1(a) as proposed as it relates to attempted conduct, except to address the mental state applicable to attempted conduct by placing the attempted conduct described in paragraphs (3) and (4) of proposed Rule 9j–1 into a standalone paragraph (5) in the final rule.¹⁴⁸

The inclusion of attempted conduct in Rules 9j–1(a)(1), (2), and (5) is premised on the text of section 9(j). First, the statute expressly prohibits “engag[ing] in any fraudulent, deceptive, or manipulative act or practice, mak[ing] any fictitious quotation, or engag[ing] in any transaction, practice, or course of business which operates as a fraud or deceit upon any person” in an “attempt to induce the purchase or sale of, any security-based swap.”¹⁴⁹ Moreover, as

counterparties to security-based swap transactions as compared to the “impersonal transactions” underlying other types of security transactions; Milbank Letter at 5 (asserting that in light of the pace of activity involved in security-based swap transactions “mere human error” could lead to liability).

¹⁴⁵ *Aaron*, 446 U.S. at 696–97.

¹⁴⁶ *SEC v. Shanahan*, 646 F.3d 536, 545–46 (8th Cir. 2011).

¹⁴⁷ In addition, the affirmative defenses in Rule 9j–1(e) address some of the concerns commenters have with regard to disruption to the security-based swap and loan markets. See *infra* section II.E.

¹⁴⁸ See Rules 9j–1(a)(1) through (5). In addition, final Rule 9j–1(a) has been revised to include the prohibitions on manipulation and attempted manipulation proposed in Rule 9j–1(b) in a new paragraph (a)(6) with some revision. See *infra* section II.C. The CFTC’s antifraud and anti-manipulation rule regarding swaps similarly prohibits attempted conduct. 17 CFR 180.1.

¹⁴⁹ 15 U.S.C. 78i(j).

¹⁴⁰ See 17 CFR 230.500 *et seq.* (“Reg D”) (providing an exemption from registration under section 5 of the Securities Act for securities offered or sold by an issuer to accredited investors). See also 17 CFR 230.501(a) (defining accredited investors to include, among other things, organizations with assets in excess of \$5,000,000 and natural persons with a net worth in excess of \$1,000,000).

¹⁴¹ See, e.g., *SEC v. Ralston Purina Co.*, 346 U.S. 119 (1953) (indicating that the application of the nonpublic offering exemption under Securities Act section 4(a)(2) (at the time, section 4(1)) depended on whether the offerees were able to fend for themselves and had access to the same kind of information that would be disclosed in registration). The Court noted that such persons, by virtue of their knowledge, would not need to rely on the protections afforded by registration.

¹⁴² See *Brian A. Schmidt et al.*, Exchange Act Release No. 45330 (Jan. 24, 2002) (citing *Adena Exploration Inc. v. Sylvan*, 860 F.2d 1242, 1251 (5th Cir. 1988) (citing *Nor-Tex Agencies Inc. v. Jones*, 482 F.2d 1093 (5th Cir. 1973)); *Stier v. Smith*, 473 F.2d 1205, 1207 (5th Cir. 1973) (sophisticated investors, like all others, are entitled to the truth); *Jay Houston Meadows*, 52 SEC. 778, 785 (1996), *aff’d*, 119 F.3d 1219 (5th Cir. 1997) (rejecting arguments that the antifraud provisions do not apply to customers who are experienced or sophisticated).

¹⁴³ The same is true with respect to Rules 9j–1(a)(1) and (2) and section 10(b) of the Exchange Act, and Rule 10b–5 thereunder, which the Supreme Court also addressed in *Aaron*.

¹⁴⁴ See MFA Letter at 12 (addressing the sophistication of and personal relationships of

¹³⁶ *Id.* at 696–97.

¹³⁷ See, e.g., LSTA Letter at 6 (arguing that a scienter standard would address concerns that a lender would be subject to negligence claims as a result of the “fluid nature” of security-based swap or loan transactions that may be subject to private negotiations, restructuring, or amendment at any given time); MFA Letter at 12–13 (arguing that sections 17(a)(2) and (3) of the Securities Act apply only to purchases or sales of securities and not to the performance of interim obligations, and also to impersonal transactions with no relationship between parties, all of which suit a negligence standard as compared to security-based swap transactions). Commenters were also concerned that a negligence standard would chill or be disruptive to the market. See MFA Letter at 13.

¹³⁸ See *supra* section I.B.

¹³⁹ See, e.g., MFA Letter at 13 (arguing that the sophistication of and personal relationships of counterparties to security-based swap transactions supported a scienter standard).

discussed above, courts have determined that an act, practice, transaction, or course of business can be fraudulent, deceptive, or manipulative, or operate as a fraud or deceit—and thus violate antifraud provisions of the securities laws—regardless of whether it succeeds in its aims.¹⁵⁰

Second, section 9(j) authorizes the Commission to “prescribe means reasonably designed to prevent” the fraudulent, deceptive, or manipulative conduct that the statute expressly prohibits. The Supreme Court has held that this language allows the Commission to “prohibit acts not themselves fraudulent . . . if the prohibition is ‘reasonably designed to prevent . . . acts and practices [that] are fraudulent.’”¹⁵¹ The Commission is exercising that authority in Rules 9j–1(a)(1), (2), and (5) to prohibit attempts to engage in fraudulent, deceptive, or manipulative acts, practices, transactions, or courses of business. The prohibition applies where a person, with scienter, takes a step in furtherance of a fraudulent, deceptive, or manipulative act, practice, transaction, or course of business but for some reason—including “pure fortuity”¹⁵²—that act, practice, transaction, or course of business is not completed. For example, and without limitation, the prohibition would apply where a supervisor, with scienter, directs a subordinate to make a fraudulent material misstatement or omission, but the subordinate refuses to do so.

Rule 9j–1(a)’s prohibition on such attempted misconduct recognizes that fraud, deception, and manipulation in the security-based swaps market can involve complex strategies implemented over multiple stages, as discussed above in section I.B.2. The prohibition is consistent with other provisions of the securities laws that recognize the importance of Commission intervention before the completion of a fraudulent, deceptive, or manipulative act, practice, transaction, or course of business. The Commission has the authority to seek an injunction whenever “any person is engaged or *is about to engage* in acts or practices constituting a violation of” the Exchange Act or Securities Act.¹⁵³ Rule

9j–1(a)’s prohibition of attempts provides the Commission with an additional tool to prevent such misconduct before any harm comes to the security-based swap market or market participants.

One commenter argued against applying the negligence standard applicable to the misconduct prohibited by Rules 9j–1(a)(3) and (4) to attempts to engage in that misconduct because it “may capture conduct that is not itself fraudulent or manipulative” but rather “legitimate business activities” and would have a “chilling effect on the market for security-based swaps.”¹⁵⁴ Another commenter noted that sections 17(a)(2) and (3) of the Securities Act do not prohibit “attempts” and that “the Commission should either eliminate the reference to attempts in Rules 9j–1(a)(3) and (4)” or clarify the standard required for liability for attempted conduct prohibited under those paragraphs of Rule 9j–1.¹⁵⁵ Similarly, one commenter believed that including attempts within the scope of conduct covered by Rule 9j–1 was broader than the scope of conduct covered by section 17(a) of the Securities Act and warranted the application of an intent standard.¹⁵⁶

Although, as discussed above, the Commission disagrees with assertions that a different standard would capture legitimate business decisions,¹⁵⁷ we nevertheless agree that scienter is the proper standard for attempts at conduct that would violate paragraphs (a)(3) or (a)(4) of final Rule 9j–1.¹⁵⁸ Therefore, while final Rule 9j–1 retains the non-scienter-based standard for the underlying conduct described in paragraphs (a)(3) and (4), the Commission is revising the final rule in order to separate the attempted conduct from paragraphs (a)(3) and (4) of proposed Rule 9j–1 into a new

fraud that failed, without proof of actual loss to any victim.”).

¹⁵⁴ LSTA Letter at 7.

¹⁵⁵ See IIB–ISDA–SIFMA Letter at 13 (arguing that “[p]arties cannot be held to a standard of strict liability with regards to fluid discussions in the course of negotiating complex transactions—not to mention the potential for good faith mistakes to arise in connection with ongoing payment and delivery obligations”).

¹⁵⁶ See MFA Letter at 12. See also IIB–ISDA–SIFMA Letter at 13 (arguing for a different standard for attempted conduct).

¹⁵⁷ See *supra* notes 144–147 and accompanying text.

¹⁵⁸ In other contexts, courts have recognized that a scienter standard may be appropriate for attempts even when it is not required for the violation attempted. See, e.g., *United States v. Cote*, 504 F.3d 682, 687 (7th Cir. 2007). See also *United States v. Gracidas-Ulibarry*, 231 F.3d 1188, 1192 (9th Cir. 2000) (recognizing “the doctrine that the crime of attempt requires a showing of specific intent even if the crime attempted does not” (internal quotation marks omitted)).

paragraph (a)(5). Scienter is the standard that will apply to Rule 9j–1(a)(5).

B. Prohibition on Price Manipulation

1. Proposed Approach

Partly in response to manufactured credit events and other opportunistic CDS strategies observed over the last decade,¹⁵⁹ paragraph (b) of proposed Rule 9j–1 was designed to address price manipulation and attempted price manipulation, similar to 17 CFR 180.2 (“CFTC Rule 180.2”).¹⁶⁰ Paragraph (b) of proposed Rule 9j–1 would have made it unlawful for any person to, directly or indirectly, manipulate or attempt to manipulate the price or valuation of any security-based swap, or any payment or delivery related thereto.

Proposed Rule 9j–1(b) was designed to capture misconduct such as situations in which a payment under the security-based swap is intentionally or recklessly distorted for the benefit of one of the security-based swap counterparties or situations in which a person intentionally or recklessly causes or avoids the purchase or sale of a security-based swap for the benefit of one counterparty. The proposed rule was not designed to capture affirmative actions taken in the ordinary course of a security-based swap transaction or the reference underlying security.¹⁶¹ In this regard, the 2021 Proposing Release stated that a determination as to whether manipulation or attempted manipulation under Rule 9j–1(b) occurred would largely depend on the facts and circumstances of each particular situation. However, as a general matter the Commission would expect to use its authority to bring an enforcement action under Rule 9j–1(b) when a party took action for the purposes of avoiding or causing, or increasing or decreasing, a payment under a security-based swap in a manner that would not have occurred but for such actions, or when an action appeared to be designed almost exclusively to harm a counterparty.¹⁶² The Commission specifically stated in the 2021 Proposing Release that its intent was not to discourage lenders and prospective lenders from discussing or

¹⁵⁹ See *supra* section I.B.2. See also 2021 Proposing Release, 87 FR at 6654–55 (discussing the manufactured credit events and other opportunistic strategies in the CDS market identified by the Commission that “may adversely affect the integrity, confidence, and reputation of the credit derivatives markets”) (quoting the 2019 Joint Statement). To be clear, Rule 9j–1, including Rule 9j–1(b), applies to all security-based swaps and is not limited to CDS.

¹⁶⁰ See 17 CFR 180.2.

¹⁶¹ See 2021 Proposing Release, 87 FR at 6663.

¹⁶² *Id.*

¹⁵⁰ See *supra* note 112.

¹⁵¹ *O’Hagan*, 521 U.S. at 673 (quoting a similar provision in Exchange Act section 14(e), 15 U.S.C. 78n(e)). See also *id.* at 672–73 (“A prophylactic measure, because its mission is to prevent, typically encompasses more than the core activity prohibited.”).

¹⁵² *Kuehnert*, 412 F.2d at 704.

¹⁵³ 15 U.S.C. 78u(d) (emphasis added) (Exchange Act); 15 U.S.C. 77t(b) (Securities Act). See, e.g., *Kuehnert*, 412 F.2d at 704 (“The Commission may act . . . to enjoin a potential fraud or prosecute a

providing financing or other forms of relief to reference entities to avoid defaulting on their debt.

2. Commission Action

The Commission is adopting a price manipulation rule as proposed in Rule 9j-1(b), but as a new paragraph (6) to Rule 9j-1(a). Consistent with the revisions to Rule 9j-1(a) discussed above in section II.A, the placement of the price manipulation rule in a new paragraph to Rule 9j-1(a), rather than in standalone paragraph 9j-1(b) as proposed, clarifies that the prohibited manipulative conduct must occur in connection with effecting, or attempting to effect a transaction in any security-based swap or in connection with purchasing or selling, or inducing or attempting to induce the purchase or sale, of any security-based swap.¹⁶³ We discuss this change in more detail below.

The Commission received multiple comment letters specifically addressing paragraph (b) of proposed Rule 9j-1. One commenter was supportive of proposed Rule 9j-1(b) and the application of a “facts and circumstances” analysis to determine whether conduct in connection with a security-based swap is manipulative.¹⁶⁴ Another commenter supported the Commission’s addition of paragraph (b) to “better protect the fairness of markets, and better enable appropriate enforcement to police abuses in the swaps markets.”¹⁶⁵

However, most of the comments addressing paragraph (b) of proposed Rule 9j-1 argued against the new provision or asked for added clarity.¹⁶⁶ One commenter argued that the Commission’s guidance with regard to the standard to be applied to determine liability under the proposed rule was insufficient and that it was unclear how courts would apply the standard absent a “deceptive intent” requirement.¹⁶⁷

The Commission has carefully considered the comments. The Commission is adopting final Rule 9j-1(a)(6) to prohibit manipulation and attempted manipulation of the price or valuation of any security-based swap, including any payment or delivery related thereto, in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap. The Commission will apply a scienter standard—which includes intentional or reckless misconduct—to determine whether conduct is in violation of final Rule 9j-1(a)(6).¹⁶⁸

Many of the commenters critical of proposed Rule 9j-1(b) believed that it was too broad and would lack clarity in application, thereby leading to a chilling effect on the security-based swap market and the credit market.¹⁶⁹ Several commenters focused on the “facts and circumstances analysis” described by the Commission in proposing Rule 9j-1(b) for determining whether a violation of the rule has occurred. In general, these commenters believed that the facts and circumstances test was not an adequate standard to determine when manipulation or attempted manipulation prohibited by proposed Rule 9j-1(b) occurred. One commenter pointed to the standard articulated by the CFTC in the enforcement of CFTC Rule 180.2 to argue for a clearer standard regarding manipulative conduct.¹⁷⁰ When adopting CFTC Rule

artificially affecting market activity or prices, with deceptive intent being an essential element for conduct to be considered “manipulative”).

¹⁶⁸ Courts have found that use of the term “manipulative” in the statute would evidence a Congressional intent to proscribe only knowing or intentional misconduct and that, accordingly, the Commission must establish that the misconduct was made with scienter. *See, e.g., Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976). The Supreme Court has defined scienter as “a mental state embracing intent to deceive, manipulate or defraud.” *Id.* In addition, scienter may also be established by a finding of recklessness. *See, e.g., Sunstrand Corp. v. Sun Chemical Corp.*, 533 F.2d 1033, 1045 (7th Cir. 1977).

¹⁶⁹ *See, e.g.,* Milbank Letter at 2 (arguing that the provision is overbroad and ambiguous and that the Commission should provide “additional clarity as to the standard that would apply to claims brought under proposed Rule 9j-1(b)”; MFA Letter at 17–18 (positing that the scope of the provision is overly broad and that “market participants will reduce their lending activity as well as their security-based swap and securities market activity, or avoid certain markets altogether”); LSTA Letter at 6 (finding that the provision introduces additional uncertainty for lenders).

¹⁷⁰ *See* MFA Letter at 18 (“The CFTC’s anti-manipulation rules applicable to swap transactions, which are similar and analogous to security-based swaps in many respects, set out a much clearer standard regarding manipulative conduct.”). CFTC Rule 180.2 addresses price manipulation and provides that “[i]t shall be unlawful for any person,

180.2, the CFTC reiterated that it would be guided by a four-part test for manipulation that it had developed in case law under sections 6(c)¹⁷¹ and 9(a)(2)¹⁷² of the Commodity Exchange Act to determine whether to apply CFTC Rule 180.2. Under this four-part test, to bring action, the CFTC would consider “(1) [t]hat the accused had the ability to influence market prices; (2) that the accused specifically intended to create or effect a price or price trend that does not reflect legitimate forces of supply and demand; (3) that artificial prices existed; and (4) that the accused caused the artificial prices.”¹⁷³ Another commenter pointed to the amended definition of “Failure to Pay” in the ISDA Credit Derivatives Definition as an example of the type of guidance the commenter believed would be helpful to market participants in determining what actions may be construed as misconduct or manipulation.¹⁷⁴

Similarly, one commenter believed that proposed Rule 9j-1(b) included a “manipulation standard that is new to securities markets” and requested further guidance or definition to avoid “the chilling effect that a poorly-understood standard could have on legitimate conduct.”¹⁷⁵ In the commenter’s view, “the Commission should articulate as precisely as possible (a) what potential conduct or activity is targeted, (b) which market participants would be harmed by it, and (c) why it is that the existing market infrastructure (whether the existing anti-

directly or indirectly, to manipulate or attempt to manipulate the price of any swap, or of any commodity in interstate commerce, or for future delivery on or subject to the rules of any registered entity.” Prohibition on the Employment, or Attempted Employment, of Manipulative and Deceptive Devices and Prohibition on Price Manipulation, 76 FR 41398, 41707 (July 14, 2011) (“CFTC Rule 180.2 Adopting Release”).

¹⁷¹ 7 U.S.C. 6c.

¹⁷² 7 U.S.C. 13(a)(2).

¹⁷³ *See* CFTC Rule 180.2 Adopting Release, 76 FR at 41407. In addition, a violation of CFTC Rule 180.2 requires a showing of “specific intent.” *Id.* (“[T]he CFTC reaffirms the requirement under final Rule 180.2 that a person must act with the requisite specific intent. In other words, recklessness will not suffice under final Rule 180.2 as it will under final Rule 180.1.”). In contrast, for purposes of liability under Rule 9j-1, scienter includes recklessness as established by a long line of case law. *See supra* note 129.

¹⁷⁴ Letter from Jennifer Han, Managed Funds Association, dated July 8, 2022 (“July 2022 MFA Letter”), at 5–7. In 2019, ISDA introduced amendments to its Credit Derivatives Definitions designed to address certain issues related to manufactured credit events, which ISDA termed “narrowly tailored credit events” (“ISDA Amendments”). *See* 2019 Narrowly Tailored Credit Event Supplement to the 2014 ISDA Credit Derivatives Definition (July 15, 2019), available at <https://www.isda.org/a/KDqME/Final-NTCE-Supplement.pdf>.

¹⁷⁵ IIB-ISDA-SIFMA Letter at 13.

¹⁶³ *See* Rule 9j-1(a)(6).

¹⁶⁴ *See* Fletcher Letter at 2 (stating that a facts and circumstances “approach avoids bright-line rules that potentially create opportunities to engage in manipulative behavior within the letter but not the spirit of the law, and provides the staff of the Commission with the flexibility it needs to evaluate transactions in an ever-evolving marketplace”).

¹⁶⁵ AFRED Letter at 4–5 (stating specifically that Rule 9j-1 would enable the Commission “to crack down on fraudulent conduct in the [CDS] market that unnecessarily triggers a counterparty to post collateral related to a default for the CDS buyers’ benefit”).

¹⁶⁶ *See* Milbank Letter at 2–5; MFA Letter at 17–18; LSTA Letter at 6; IIB-ISDA-SIFMA Letter at 13–15.

¹⁶⁷ Milbank Letter at 3 (citing case law in which “anti-manipulation provisions of existing securities laws are generally interpreted . . . to prohibit conduct that is intended to deceive investors by

fraud rules or the provisions of the relevant contracts) does not already provide sufficient protection.”¹⁷⁶ A significant concern for the commenter was whether market participants would be able to determine that their actions were manipulative and in violation of proposed Rule 9j–1(b). Absent a clear standard, they argued that market participants may determine to reduce their activity, which would have broad negative impacts on liquidity in the security-based swap market and broader economy.¹⁷⁷ Finally, the commenter requested that the Commission provide guidance with regard to the types of conduct or activities that would violate proposed Rule 9j–1(b) and those that would not violate proposed Rule 9j–1(b) under any implemented “facts and circumstances” test.¹⁷⁸ A separate commenter requested that the Commission “tailor” proposed Rule 9j–1(b) so that it includes a specific description of what constitutes manipulative conduct.¹⁷⁹

The Commission is revising the price manipulation provision, originally proposed as Rule 9j–1(b) and adopted as final Rule 9j–1(a)(6), in response to the comments above. Consistent with the revisions to final Rule 9j–1(a) discussed above in section II.A, Rule 9j–1(a)(6) will apply to conduct undertaken in connection with effecting or attempting to effect a transaction in any security-based swap, and to purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security based-swap).¹⁸⁰ As the Supreme Court has stated, “fraudulent manipulation of [securities] prices . . . unquestionably qualifies as a fraud ‘in connection with the purchase or sale’ of securities.”¹⁸¹ Rule 9j–1(a)(6) also prohibits the manipulation (or attempted manipulation) of the valuation of any security-based swap, or any payment or

delivery related thereto, to the extent such misconduct is in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap.¹⁸²

A determination as to whether a person has violated final Rule 9j–1(a)(6) will depend on the facts and circumstances of each particular situation. The assessment of facts and circumstances is an objective evaluation that considers all relevant information surrounding the alleged misconduct, including both quantitative and qualitative factors, to determine whether prohibited manipulation is present. A “facts and circumstances” analysis will provide the Commission with the flexibility it needs to address an evolving security-based swap market, including the ever-changing CDS market, and potential misconduct in those markets. Bright line rules or tests, on the other hand, may artificially exclude manipulative and attempted manipulative conduct and could create a roadmap for market participants to avoid liability for manipulative actions. A substantial body of case law regarding manipulative behavior exists with regard to other antifraud and anti-manipulation provisions in the Securities Act and Exchange Act to which the Commission will look to assess whether a violation of Rule 9j–1(a)(6) has occurred.¹⁸³ In addition, the Commission reiterates that case law requires a showing of scienter to bring an action for manipulation or attempted manipulation and that it will apply a scienter standard to determine whether conduct is in violation of Rule 9j–1(a)(6).

Also, as noted, commenters encouraged the Commission to explicitly recognize certain market activities as legitimate.¹⁸⁴ The Commission declines to carve out from the application of Rule 9j–1(a)(6)

categories of market activities based on hypothetical fact patterns as requested by commenters. Liability under Rule 9j–1(a)(6) will depend upon an analysis of *all* relevant information. A different approach could artificially exclude manipulative conduct, particularly given the complex fact patterns generally at issue in many security-based swap transactions. As discussed in the 2021 Proposing Release, Rule 9j–1(a)(6) applies to actions taken outside the ordinary course of a typical lender-borrower relationship, such as an action taken for the purposes of avoiding or causing, or increasing or decreasing, a payment under a security-based swap in a manner that would not have occurred but for such actions, or when an action appears to be designed almost exclusively to harm counterparties, and is not intended to discourage lenders from discussing or providing financing or relief to avoid default.¹⁸⁵ Moreover, the fact that the Commission will apply a scienter standard for liability under Rule 9j–1(a)(6) should lessen concerns regarding any “chilling effects” of the new rule.¹⁸⁶ Further, as discussed in section II.E.2, the affirmative defenses of final Rule 9j–1(e) do not apply to the anti-manipulation provision in Rule 9j–1(a)(6) because paragraph (a)(6) does not apply to affirmative actions taken in the ordinary course of a security-based swap transaction or the reference underlying security while aware of material nonpublic information. To be clear, Rule 9j–1(a)(6) will require that security-based swap market participants take care that their legitimate market activities remain within the scope of the typical lender-borrower relationship and do not cross the line into prohibited manipulation. However, the use of a facts and circumstances analysis, along with the use of a scienter standard, to identify manipulative conduct addresses commenters concerns that legitimate market activities would be captured by the prohibitions of Rule 9j–1(a)(6) or otherwise chilled.

However, to further address commenter concerns, the Commission reiterates that Rule 9j–1(a)(6) prohibits, among other things, a situation where a person (or group of persons) intentionally or recklessly causes or

¹⁷⁶ *Id.* at 14 (stating that care should be taken to correctly analyze the potential impact of new manipulation standards such as that in Rule 9j–1(b)).

¹⁷⁷ *Id.* at 13–14.

¹⁷⁸ *Id.* at 16.

¹⁷⁹ See MFA July 2022 Letter at 10. The commenter also believed that the Commission should re-propose Rule 9j–1(b) for public comment to allow market participants “to adequately assess the potential impact of [proposed Rule 9j–1(b)] on the security-based swap markets and . . . on the broader market for corporate debt.” *Id.*

¹⁸⁰ See *supra* section II.A.

¹⁸¹ *Dabit*, 547 U.S. at 89.

¹⁸² The Commission has the authority to prohibit attempted manipulation based on section 9(j)’s application to “attempt[s] to induce the purchase or sale of” any security-based swap, as well as case law establishing that manipulative conduct need not be successful to violate the securities laws. See *supra* note 112.

¹⁸³ See, e.g., *Ernst & Ernst v. Hochfelder*, 425 U.S. 185 (1976); *Markowski v. SEC*, 274 F.3d 525 (D.C. Cir. 2001); *United States v. Mulheren*, 938 F.2d 364 (2d Cir. 1991); *SEC v. Malenfant*, 784 F. Supp. 141, 144 (S.D.N.Y. 1992); *SEC v. Markusen*, 2016 U.S. Dist. LEXIS 55419 (D. Minn. Apr. 25, 2016); *Sharette v. Credit Suisse Intern.*, 127 F. Supp. 3d 60 (S.D.N.Y. 2015); *ATSI Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87 (2d Cir. 2007); *Wilson v. Merrill Lynch & Co.*, 671 F.3d 120 (2d Cir. 2011); *SEC v. Schiffer*, 1998 U.S. Dist. LEXIS 8579 (S.D.N.Y. June 10, 1998).

¹⁸⁴ See IIB-ISDA-SIFMA Letter at 15–23.

¹⁸⁵ See 2021 Proposing Release, 87 FR at 6663. As discussed above, the text of revised Rule 9j–1(a) also specifies that such actions must occur in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap.

¹⁸⁶ See Letter from Som-lok Leung, International Association of Credit Portfolio Managers (“IACPM”), dated Mar. 21, 2022 (“IACPM Letter”), at 4; MFA Letter at 8–10; LSTA Letter at 5, 7–10; IIB-ISDA-SIFMA Letter at 13–22.

avoids the purchase or sale of a security-based swap for the benefit of a counterparty, or to harm a counterparty, to a security-based swap. This may include, for example, orphaning a CDS,¹⁸⁷ avoiding termination of a CDS for a period of time, or causing the termination of a CDS. But a person simply profiting from a CDS position after a company's bankruptcy, which such person could have prevented by participating in a financing to the company, without more, is not in and of itself improper conduct for purposes of Rule 9j-1(a)(6).

The Commission also recognizes that reference entities often rely on financing and other forms of relief to avoid defaulting on their debt. We understand that CDS transactions are an important means by which debt holders hedge their underlying debt instruments, and that the absence of such hedging opportunities could impact prospective investors' willingness and ability to invest in that underlying market. The final rule is not intended to discourage lenders and prospective lenders from discussing or providing such financing or relief, even when those persons also hold CDS positions. Rather, the Commission is adopting Rule 9j-1(a)(6) to account for actions taken outside the ordinary course of a typical lender-borrower relationship (or a prospective lender-borrower relationship). Although, as discussed, any such determination would need to be based on the facts and circumstances of a particular situation, as a general matter an action that appears to be designed almost exclusively to harm one or more CDS counterparties would likely fall within the prohibition in Rule 9j-1(a)(6). Security-based swap market participants should and can take care that their legitimate market activities remain within the scope of the typical lender-borrower relationship and do not cross the line into prohibited manipulation. Using a "facts and circumstances" analysis to identify conduct that is prohibited by Rule 9j-1(a)(6), the Commission will consider all relevant facts in any attempt to determine whether prohibited manipulation or attempted manipulation has occurred. Further, the Commission will apply a scienter

standard, which will work to eliminate legitimate conduct from the scope of Rule 9j-1(a)(6). As discussed above, the adoption of a "facts and circumstances" analysis is appropriate given the complex fact patterns in many security-based swap transactions.

Proposed Rule 9j-1(b) was intended to address, among other things, a number of the manufactured credit events or other opportunistic strategies in the CDS market observed over the last decade.¹⁸⁸ In re-proposing Rule 9j-1, the Commission provided specific examples of manufactured or other opportunistic CDS strategies that had been reported by academics and the press.¹⁸⁹ Commenters raised concerns both that industry efforts, such as the ISDA Amendments and anti-net short provisions, have successfully addressed opportunistic strategies such as those described in the 2021 Proposing Release,¹⁹⁰ and that the description of the manufactured credit events or opportunistic strategies identified by the Commission were "overly-broad and capture legitimate market activities."¹⁹¹ One commenter asked the Commission to "refine the descriptions of" manufactured credit events or opportunistic strategies that they believe are too broad and have been addressed by industry efforts.¹⁹² With regard to industry efforts, the anti-net short provisions and ISDA Amendments are narrowly focused and have limited ability to reduce fraudulent and manipulative activity in the security-based swap market. The ISDA Amendments do not address all of the concerns identified in the 2019 Joint Statement, including, but not limited to, addressing opportunistic strategies that do not involve narrowly tailored credit events.¹⁹³ Anti-net short provisions are limited to syndicated bank loans and would not apply to fraudulent activity in the security-based swap market that does not involve such loans. Thus, even if these industry efforts were successful in reducing fraudulent activity, their impact likely would be limited by their narrow scope. In response to requests to refine the descriptions of manufactured credit events in the 2021 Proposing Release, the Commission agrees that

there may be circumstances in which the types of conduct described may not be the result of manipulation or attempted manipulation; however, the facts and circumstances analysis and scienter standard sufficiently tailor final Rule 9j-1(a)(6) to properly capture manipulative conduct. Therefore, the Commission declines to revise the descriptions.

One commenter requested that the "valuation" prong of proposed Rule 9j-1(b) be removed because "a prohibition on manipulation of the 'valuation' of an asset does not exist in any U.S. regulatory context and would require a new body of case law to be formed to determine how any such new prohibition should be interpreted."¹⁹⁴ The commenter argued that case law focuses on divergences between price and value and that "no analogy can be drawn in cases where it is the change in value that is prohibited."¹⁹⁵ The Commission declines to remove the manipulation of a security-based swap's valuation from the scope of Rule 9j-1(a)(6) because the pricing and valuation of security-based swaps are intrinsically connected. For example, although CDS pricing can be complex, "[t]he basic idea of CDS pricing is that the present value of all the CDS premium payments should equal to the present value of the expected payoff from the CDS for the [net present value] to be 0 for both parties of the contract (resulting in each party being equally well off)."¹⁹⁶ In other words, a CDS typically is priced to allow the protection seller to recover its potential cash outflows upon a credit event and termination of the CDS, or its "expected loss." The protection seller will determine the value of the expected loss based on several factors, including the likelihood of default and cost of capital. The value of the expected loss drives the price of the CDS and the payout upon termination of the CDS. Similarly, the price of a TRS typically is the difference between the present value of both "legs" of the transaction's cash flows. Therefore, actions to manipulate price will affect valuation and vice versa. Additionally, market participants

¹⁸⁸ See 2021 Proposing Release, 87 FR at 6663.

¹⁸⁹ See *supra* section I.B.2. See also 2021

Proposing Release, 87 FR at 6654–55 (describing in more detail examples of manufactured credit events and other opportunistic strategies in the CDS market reported by academics and the press).

¹⁹⁰ See IIB-ISDA-SIFMA Letter at 19–20; LSTA Letter at 4; MFA July 2022 Letter at 4–10; Milbank Letter at 6.

¹⁹¹ IIB-ISDA-SIFMA Letter at 20–23.

¹⁹² See IIB-ISDA-SIFMA Letter at 19.

¹⁹³ See 2021 Proposing Release, 87 FR at 6655 n.31.

¹⁹⁴ Milbank Letter at 3 (citing to *Santa Fe Industries, Inc. v. Green*, 430 U.S. 462, 476 (1977), to argue that "'[m]anipulation' is 'virtually a term of art when used in connection with securities markets' The term refers generally to practices, such as wash sales, matched orders, or rigged prices, that are intended to mislead investors by artificially affecting market activity").

¹⁹⁵ Milbank Letter at 3.

¹⁹⁶ Yuan Wen and Jacob Kinsella, *Credit Default Swap—Pricing Theory, Real Data Analysis and Classroom Applications Using Bloomberg Terminal*, available at https://data.bloomberglp.com/bat/sites/3/2016/10/WhitePaper_Wen.pdf.

¹⁸⁷ "Orphaning" a CDS refers to a situation where the debt of a reference entity is eliminated or reduced for the purposes of moving the price of CDS. The end result of such activity is that CDS buyers continue to pay (and CDS sellers continue to receive) premiums on CDS that will never default. Similarly, a CDS protection seller could offer financing to the company to avoid a credit event and subsequent CDS payout, with the financing timed so that the company's bankruptcy is merely delayed until after the CDS expires.

may rely on models to price or value the swap.¹⁹⁷ This suggests that “valuation” of a security-based swap has a role in the market and should be included in the anti-manipulation provisions of Rule 9j–1(a)(6). Further, by prohibiting the manipulation of a security-based swap’s valuation, Rule 9j–1(a)(6) will help to prevent manipulation of payments and deliveries under a security-based swap “from distorting the price and market for such security-based swaps, as well as for the reference underlying, and improperly interfering with the independent and proper functioning of the markets.”¹⁹⁸

Rule 9j–1(a)(6) prohibits manipulation in connection with effecting or attempting to effect a transaction in, any security-based swap, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap, which may include intentionally or recklessly distorting payments related to a security-based swap to benefit, or harm, one of the security-based swap counterparties, or actions that serve little to no economic purpose other than to artificially influence the composition of the deliverable obligations in a CDS auction and affect the security-based swap’s valuation and price. To remove the valuation prong from final Rule 9j–1(a)(6) would create a gap in the prohibition against the manipulation or attempted manipulation of prices in the security-based swap market.

D. Liability Under Rules 9j–1(b) and (c)

1. Proposed Approach

The Commission included paragraphs (c) and (d) of re-proposed Rule 9j–1 to make it clear that market participants could not avoid liability under the rule by effecting a fraudulent scheme through the purchase or sale of an underlying security, rather than the purchase or sale of the security-based swap on which it is based, and vice versa. The first of those two provisions would have provided that a person could not escape liability for trading based on possession of material nonpublic information about a security

by purchasing or selling a security-based swap based on that security (as opposed to trading in the security itself). The second provision would have provided that a person could not escape liability under section 9(j) or Rule 9j–1 by purchasing or selling the underlying security (as opposed to purchasing or selling a security-based swap that is based on that security).

2. Commission Action

One commenter specifically addressed these provisions and was supportive, noting that the antifraud and anti-manipulation provisions in proposed Rules 9j–1(a) and (b) would be enhanced by the addition of proposed Rules 9j–1(c) and (d).¹⁹⁹ In contrast, one commenter questioned the Commission’s authority to extend the prohibitions of Rule 9j–1 to the purchase and sale of underlying securities.²⁰⁰ After considering these comments, the Commission adopts Rules 9j–1(c) and (d) largely as proposed but renumbered as final Rules 9j–1(b) and (c), respectively.

a. Rule 9j–1(b)

The Commission is adopting Rule 9j–1(b), as proposed in paragraph (c). Final Rule 9j–1(b) provides that wherever communicating, or purchasing or selling a security (other than a security-based swap) while in possession of, material nonpublic information would violate, or result in liability to any purchaser or seller of the security under either the Exchange Act or the Securities Act, or any rule or regulation thereunder, such conduct in connection with a purchase or sale of a security-based swap with respect to such security or with respect to a group or index of securities including such security shall also violate, and result in comparable liability to any purchaser or seller of that security under such provision, rule, or regulation.²⁰¹

Although generally a situation where a person uses material nonpublic information about a security in connection with the purchase or sale of a security-based swap would be subject to the existing antifraud authority under the Federal securities laws, particularly section 10(b) of the Exchange Act, and Rule 10b–5 thereunder, market participants also would benefit from a clarified interpretation of that statutory provision in this rulemaking.²⁰² This is

particularly true given that the issuer of a security-based swap (*i.e.*, each counterparty to the transaction) is different from the issuer of the underlying security (*i.e.*, the reference entity). Accordingly, the Commission is now adopting Rule 9j–1(b) to provide that a person making a purchase or sale of a security-based swap while in possession of material nonpublic information with respect to the security underlying such security-based swap is subject to liability.

b. Rule 9j–1(c)

The Commission also is adopting Rule 9j–1(c) largely as it was proposed as paragraph (d), with a clarifying edit as discussed below.²⁰³ Final Rule 9j–1(c) will address a situation similar to the one described above. Specifically, it provides that wherever taking any of the actions set forth in Rule 9j–1(a) involving a security-based swap would violate, or result in liability under section 9(j) of the Exchange Act or Rule 9j–1(a), such conduct, when taken by a counterparty to such security-based swap (or any affiliate of, or a person acting in concert with, such security-based swap counterparty in furtherance of such prohibited activity), in connection with a purchase or sale of a security, loan, or group or index of securities on which such security-based swap is based shall also violate, and shall be deemed a violation of, section 9(j) or Rule 9j–1(a). The adopted rule text is modified from the 2021 Proposing Release to now include a reference to “loan.” The addition clarifies the scope of underlying products that apply, and is consistent with the underlying products included in the definition of “security-based

laws by making purchases or sales in a swap on a broad-based index containing the security (*e.g.*, the S&P 500), which would be a security-based swap agreement, whereas the statute is silent as to the permissibility of trading on such material nonpublic information by making purchases or sales of a security-based swap (*e.g.*, a swap on the security itself). The Commission does not construe that silence as an intent to exclude security-based swaps from the scope of section 20(d) and the Commission has the authority under section 9(j) to prescribe means reasonably designed to prevent fraud, manipulation, or deceit with respect to security-based swap transactions. In addition, Section 9(j) makes it unlawful for any person to directly or indirectly take the actions described in that section.

²⁰³ In addition, final Rule 9j–1(c) includes non-substantive corrections to punctuation and two non-substantive revisions: (1) the word “whenever” at the start of the paragraph has been replaced with the word “wherever” to be consistent with the language in paragraph (b); and (2) the references to “paragraphs (a) or (b)” of Rule 9j–1 have been replaced with just a reference to “paragraph (a)” to reflect the placement of paragraph (b) of proposed Rule 9j–1 into a new paragraph (a)(6) of final Rule 9j–1.

¹⁹⁷ The Commission has previously recognized that market participants may rely on models for pricing and valuation of security-based swaps. *See, e.g.*, Business Conduct Standards Adopting Release, 81 FR at 29988 (in the context of daily marks, stating that “even if the mark is calculated based on internal models or such indices, its provision by the SBS Entity will further the goal of providing helpful transparency into the SBS Entity’s pricing and valuation of the security-based swap by providing a helpful reference point that the SBS Entity’s counterparty can take into account when evaluating the pricing and valuation of the SBS.”).

¹⁹⁸ 2010 Rule 9j–1 Proposing Release, 75 FR at 68565–66.

¹⁹⁹ *See* Better Markets Letter at 9.

²⁰⁰ *See* MFA Letter at 8–9.

²⁰¹ Final Rule 9j–1(b) includes non-substantive corrections to punctuation.

²⁰² Pursuant to section 20(d) of the Exchange Act, a person with material nonpublic information about a security cannot avoid liability under the securities

swap” in section 3(a)(68)(A) of the Exchange Act.²⁰⁴

This provision prevents a person from escaping liability under section 9(j) or Rule 9j–1(a) with respect to a security-based swap by limiting all of its actions to purchases or sales of the security, loan, or narrow-based security index underlying that security-based swap. For example, if a person with an existing total return swap on equity securities issued by XYZ Corporation subsequently engages in a number of wash trades to artificially inflate the price of the equity securities in order to benefit from the manipulated price by way of their existing security-based swap position, such person would be liable for violations of Exchange Act section 9(j) and Rule 9j–1 regardless of the fact the manipulation was conducted through purchases or sales of the equity securities.

In response to the commenter who questioned the Commission’s authority to extend the prohibitions of Rule 9j–1 to the purchase or sale of underlying securities,²⁰⁵ the Commission clarifies that final Rule 9j–1(c) does not create a separate category of prohibited activity absent a connection to security-based swaps. Rather, this provision is reasonably designed to prevent fraud, manipulation, or deceit with respect to security-based swaps where that misconduct is accomplished through transactions in the underlying security, loan, or group or index of securities. This provision is necessary because security-based swaps by their nature are tied intrinsically to activity in the markets for other securities.

Moreover, this provision does not impose liability on a person for violations of section 9(j) of the Exchange Act and Rule 9j–1 based solely on the impact of that person’s purchases or sales on the equity, debt, or loan markets. The rule states that the person engaged in prohibited activities in the equity, debt, or loan markets must be a counterparty to a security-based swap that references such equity or debt securities or loan, or be an affiliate of, or a person acting in concert with, such security-based swap counterparty in furtherance of such prohibited activity. Accordingly, the Commission would analyze whether transactions in the underlying equity or debt securities or loan have been used as the mechanism to violate section 9(j) and Rule 9j–1. The Commission would also analyze the same transactions to determine whether they independently violate other antifraud and anti-manipulation

provisions of the securities laws—including sections 9 and 10(b) of the Exchange Act, and Rule 10b–5 thereunder, as well as section 17(a) of the Securities Act.

E. Safe Harbors and Affirmative Defenses

1. Proposed Approach

In response to operational concerns raised by commenters with regard to the 2010 Proposed Rule, the Commission proposed two limited safe harbors from re-proposed Rule 9j–1(a) to address situations when a counterparty to a security-based swap was required to take certain actions while in possession of material nonpublic information.²⁰⁶ First, proposed Rule 9j–1(f)(1), would have allowed a person to take action in accordance with binding contractual rights and obligations under a security-based swap (as reflected in the written security-based swap documentation governing such transaction or any amendment thereto), so long as the person could demonstrate that: (1) the security-based swap was entered into, or the amendment was made, before the person became aware of such material nonpublic information; and (2) the entry into, and the terms of, the security-based swap were themselves not a violation of any provision of proposed Rule 9j–1(a).²⁰⁷

Second, recognizing the important operational benefits and market efficiencies related to security-based swap portfolio compression, proposed Rule 9j–1(f)(2) would have provided a safe harbor for transactions effected in connection with certain types of bilateral or multilateral portfolio compression exercises.²⁰⁸ This proposed safe harbor would have provided that a person would not be liable under re-proposed Rule 9j–1(a) solely for reason of being aware of material nonpublic information for “security-based swap transactions effected by a person pursuant to a bilateral portfolio compression exercise (as defined in § 240.15Fi–1(a)) or a multilateral portfolio compression exercise (as defined in § 240.15Fi–1(j)) so long as: (i) any such transactions are consistent with all of the terms of a bilateral portfolio compression exercise or multilateral portfolio compression exercise, including as it relates to, without limitation, the transactions to be included in the exercise, the risk tolerances of the persons participating in the exercise, and the methodology

used in the exercise; and (ii) all such terms were agreed to by all participants of the bilateral portfolio compression exercise or multilateral portfolio compression exercise prior to the commencement of the applicable exercise.”²⁰⁹

2. Commission Action

As discussed above, in response to operational concerns raised in response to the 2010 Proposed Rule, the Commission included two limited safe harbors from re-proposed Rule 9j–1(a).²¹⁰ After further consideration and as described in more detail below, the Commission is not adopting either proposed safe harbor. Instead, the Commission is adopting two affirmative defenses from Rules 9j–1(a)(1) through (a)(5). One affirmative defense is for actions taken in connection with the binding contractual rights and obligations under a security-based swap (similar to the proposed safe harbor). The other affirmative defense takes account of reasonable policies and procedures that ensure that individuals making investment decisions are not engaging in prohibited conduct in final Rules 9j–1(a)(1) through (a)(5). These affirmative defenses, while not identical to the affirmative defenses under Rule 10b5–1, are similar in that they apply to situations in which a person can demonstrate that material nonpublic information did not factor into their investment decision.

Consistent with the analogous provisions of Rule 10b5–1, final Rule 9j–1 does not provide for an affirmative defense for violations of the anti-manipulation provision in Rule 9j–1(a)(6). Paragraph (a)(6) of Rule 9j–1 does not apply to actions that the affirmative defenses address: those taken in the ordinary course of a security-based swap transaction (including actions related to the reference underlying security) while aware of material nonpublic information.²¹¹

Several commenters urged the Commission to make the affirmative defenses under Rule 10b5–1 available under Rule 9j–1, to address situations in which a counterparty comes into possession of material nonpublic information during the life of a security-based swap.²¹² Rule 10b5–1 applies to

²⁰⁹ Re-proposed Rule 9j–1(f)(2); 2021 Proposing Release, 87 FR at 6662.

²¹⁰ See 2021 Proposing Release, 87 FR at 6660–62.

²¹¹ Final Rule 9j–1(a)(6) is discussed in section II.C above.

²¹² See ACLI Letter at 2, 5; IIB–ISDA–SIFMA Letter at 4–5, 10; MFA Letter at 13–16; LSTA Letter at 9; Letter from Lindsey Weber Kiljo and William

²⁰⁴ See 15 U.S.C. 78c(68)(A).

²⁰⁵ MFA Letter at 9.

²⁰⁶ See 2021 Proposing Release, 87 FR at 6662, 6662 n.87.

²⁰⁷ *Id.* at 6662.

²⁰⁸ See *id.* at 6662–63.

insider trading cases under section 10(b) of the Exchange Act, and Rule 10b-5 thereunder, and includes affirmative defenses for: (1) purchases or sales pursuant to a binding contract, an instruction to another person to execute the trade for the instructing person's account, or a written trading plan under certain conditions;²¹³ and (2) transactions by an entity if the individual making the investment decision on behalf of the entity was not aware of the material nonpublic information and the entity had implemented reasonable policies and procedures to ensure that the individuals making investment decisions would not violate insider trading laws.²¹⁴

Several commenters noted that most security-based swap market participants are global financial firms that have spent considerable resources to meet the requirements of current Rule 10b5-1(c)(2), by separating their organizations so that individuals on the public side can engage in dealing and market-making activity, while individuals on the private side are allowed to possess material nonpublic information.²¹⁵ One commenter stated that the current policies and procedures restrict access to material nonpublic information by those individuals who engage in security-based swap transactions for hedging or other purposes.²¹⁶ Since neither of the Rule 10b5-1 defenses explicitly applied to proposed Rule 9j-1 for security-based swaps, one commenter noted the "confusion and regulatory uncertainty" that would be created with the omission of a Rule 10b5-1(c)(2)-type defense from Rule 9j-1 (because identical conduct in the context of a security-based swap transaction could implicate both Rule 10b-5 and Rule 9j-1, but the affirmative defense would only be available under Rule 10b-5).²¹⁷

In addition, certain commenters expressed concern with the operational impacts of Rule 9j-1(a) on the capital and loan markets. One commenter argued that the application of proposed Rule 9j-1 to the ongoing, "non-volitional" rights and obligations that occur throughout the life of a security-based swap could "cast uncertainty on

a wide range of bona fide conduct necessary to the operation of the capital markets."²¹⁸ The commenter urged the Commission to "provide an affirmative defense for actions taken by a person in accordance with binding contractual rights and obligations under [a security-based swap] . . . or to fulfill a regulatory obligation in connection with [a security-based swap] . . . if the person did not act intentionally or recklessly in connection with such action and . . . complied in good faith with written policies and procedures reasonably designed to meet the obligation."²¹⁹ The commenter was concerned that the negligence standard applicable to re-proposed Rules 9j-1(a)(3) and (4), in particular, could lead to potential fraud liability for good faith, non-volitional conduct.²²⁰ Another commenter addressed operational concerns related to the credit markets and argued that the proposed rule would "create considerable uncertainty with respect to the legitimate business decisions of lenders and impair the [security-based swap] market and loan market."²²¹ The commenter explained that if the rule were to apply to any activity that potentially affects the stream of payments, deliveries or other ongoing obligations or rights between parties to a security-based swap, "each party will have to implement controls and mechanisms to track decisions made in connection with each payment, delivery, obligation or right as well as to track changes in its positions in the security-based swap and reference underlying."²²²

The Commission agrees with commenters that an affirmative defense similar to those available under Rule 10b5-1 (when the investment decision is not based on material nonpublic information) is important given the similarity in the antifraud provisions. The Commission also agrees that the

affirmative defenses would address concerns regarding market disruption. As a result, the Commission is adopting two affirmative defenses similar in concept to the affirmative defenses in Rule 10b5-1(c).²²³ However, the Commission is adapting the affirmative defenses for the specific context of Rule 9j-1. In particular, the Commission is not adopting an affirmative defense that is as broad as the affirmative defenses in Rule 10b5-1(c)(1). Rather, as discussed below, the Commission is limiting the relevant Rule 9j-1 affirmative defense to actions taken pursuant to binding contractual rights under the documentation governing a security-based swap. The Rule 10b5-1(c)(1) affirmative defenses relate to advance planning of purchases or sales pursuant to a binding contract, an instruction to another person to execute the trade for the instructing person's account, or a written trading plan under certain conditions.²²⁴ Those Rule 10b5-1(c)(1) affirmative defenses were created to "provide appropriate flexibility to those who would like to plan securities transactions in advance, at a time when they are not aware of material nonpublic information, and then carry out those pre-planned transactions at a later time, even if they later become aware of material nonpublic information."²²⁵ That flexibility is warranted in the context of corporate insiders and others who periodically come into possession of material nonpublic information but may want to schedule orderly trading of securities of an issuer on a liquid public market. It is not appropriate in the context of security-based swaps, which are typically bespoke, created and

²²³ Much of the development of insider trading law has resulted from court cases. The Supreme Court has stated that "[u]nder the 'traditional' or 'classical theory' of insider trading liability, [section] 10(b) and Rule 10b-5 are violated when a corporate insider trades in the securities of his corporation on the basis of material, nonpublic information." *O'Hagan*, 521 U.S. at 651-52 (*emphasis added*). See also Selective Disclosure and Insider Trading, Exchange Act Release No. 43154 (Aug. 15, 2000), 65 FR 51716, 51727 (Aug. 24, 2000) (discussing the awareness standard required for insider trading liability and adopting the definition of "on the basis" of material nonpublic information in Rule 10b5-1(b)). In this regard, any of the actions set forth in Rule 9j-1(a) with regard to a security-based swap are "on the basis of" material nonpublic information about that security-based swap, the issuer of that security-based swap, or the security underlying that security-based swap, if the person taking the action was aware of the material nonpublic information when the person took the action.

²²⁴ See Rule 10b5-1(c)(1).

²²⁵ See Insider Trading Arrangements and Related Disclosures, Exchange Act Release No. 96492 (Dec. 14, 2022), 87 FR 80362, 80363 (Dec. 29, 2022) ("Rule 10b5-1 Amendments").

C. Thum, Asset Management Group of SIFMA ("SIFMA AMG"), dated Mar. 21, 2022 ("SIFMA AMG Letter"), at 11-12.

²¹³ See 17 CFR 240.10b5-1(c)(1) ("Rule 10b5-1(c)(1)").

²¹⁴ See 17 CFR 240.10b5-1(c)(2) ("Rule 10b5-1(c)(2)").

²¹⁵ See IACPM Letter at 4; IIB-ISDA-SIFMA Letter at 5; MFA Letter at 13-14.

²¹⁶ See LSTA Letter at 9.

²¹⁷ IIB-ISDA-SIFMA Letter at 5.

²¹⁸ *Id.* at 8-10.

²¹⁹ *Id.* at 10-11, 11 n.18 (referencing a safe harbor adopted by the CFTC in connection with non-scienter fraud and manipulative prohibitions as part of its swap dealer business conduct standards).

²²⁰ *Id.* at 9. The commenter stated that it did not have the same concerns about proposed Rule 9j-1(b) (now Rule 9j-1(a)(6)), because the scienter standard applicable to that provision is "sufficient to distinguish illegitimate conduct from merely negligent acts that affect payment or delivery obligations."

²²¹ LSTA Letter at 3-10.

²²² *Id.* The LSTA supported the principles underlying section 9(j) but did not see the need for a new rule in light of existing antifraud rules and further believed that the existing antifraud rules would address several of the manufactured credit events described in the 2021 Proposing Release and that the adoption of anti-net short provisions would address other concerns. *Id.* at 3-4. The Commission believes that the affirmative defense provided by new Rule 9j-1(e)(2) will address these concerns.

issued by the counterparties, and thinly traded.

Accordingly, the Commission is adopting two affirmative defenses to liability under paragraphs (a)(1) through (a)(5) of final Rule 9j–1.

a. Affirmative Defense: Binding Contractual Obligations

First, the Commission is adopting an affirmative defense that maintains the substance of the safe harbor provision in re-proposed Rule 9j–1(f)(1), which would have applied to actions taken pursuant to binding rights and obligations in written documentation governing a security-based swap that was entered into prior to the person coming into possession of material nonpublic information. As adopted, the provision in Rule 9j–1(e)(1) (renumbered from proposed paragraph (f)) is an affirmative defense, rather than a safe harbor, to be consistent with the structure of current Rule 10b5–1(c)(1). The affirmative defense in final Rule 9j–1(e)(1) provides that actions that would otherwise violate the prohibitions of Rule 9j–1(a)(1) through (5) are not a violation “solely for reason of being aware of material nonpublic information” if such actions are “taken by a person in accordance with binding contractual rights and obligations under a security-based swap (as reflected in the written security-based swap documentation governing such transaction or any amendment thereto).”²²⁶ Under this affirmative defense, consistent with Rule 10b5–1(c)(1), a market participant may take action when aware of material nonpublic information but may avoid liability: “so long as the person demonstrates that: (i) [t]he security-based swap was entered into, or the amendment was made, before the person became aware of such material nonpublic information, and (ii) [t]he security-based swap was entered into in good faith and not as part of a plan or scheme to evade the prohibitions of [Rule 9j–1].”²²⁷

Framing this relief as an affirmative defense rather than as a safe harbor, and restricting its use to circumstances in which the security-based swap was entered into in good faith and not as part of a plan or scheme to evade the prohibitions of the rule, is consistent with Rule 10b5–1(c)(1) treatment of the defense. As discussed above, multiple commenters requested the Commission adopt affirmative defenses based on the Rule 10b5–1(c) defenses.²²⁸ Rule 10b5–

1(c)(1) provides an affirmative defense from Rule 10b–5 liability in circumstances where it is apparent that the trading was not made on the basis of material nonpublic information because “the trade was made pursuant to a binding contract, an instruction to another person to execute the trade for the instructing person’s account, or a written plan for the trading of securities . . . adopted at a time that the person was not aware of material nonpublic information.”²²⁹ Similarly, Rule 9j–1(e)(1) provides an affirmative defense from Rule 9j–1(a) liability when an action is taken not on basis of material nonpublic information, but pursuant to binding contractual rights and obligations reflected in the written documentation governing a security-based swap.

If the security-based swap was entered into in good faith and not as part of a plan or scheme to evade the prohibitions of the rule, the new Rule 9j–1(e)(1) affirmative defense will allow counterparties to take actions that are required by, and in accordance with, the written agreements governing the security-based swap (*i.e.*, actions in the normal course of the security-based swap transaction) even when aware of material nonpublic information. For example, the Rule 9j–1(e)(1) affirmative defense would apply to making a standardized coupon payment or delivering collateral to a counterparty (and would also permit the counterparty to receive the coupon payment or collateral), while such person is aware of material nonpublic information, so long as both actions are required by the terms of the transaction and documented in writing. In contrast, the affirmative defense would not apply if a counterparty took some action to fraudulently increase (in the case of the receiving counterparty) or decrease (in the case of the delivering counterparty) the amount of such payment or collateral transfer. Rule 9j–1(e) provides an affirmative defense when a person’s conduct would violate Rule 9j–1(a)(1) through (5) “solely” because he or she is “aware of material nonpublic information.” But actions to fraudulently increase or decrease

²²⁹ See Rule 10b5–1 Amendments, 87 FR 80362, 80363 (adopting revisions to the Rule 10b5–1(c)(1) affirmative defense to apply a cooling-off period on persons other than the issuer of securities subject to a plan, impose a certification requirement on directors and officers of those issuers, limit the ability of persons other than the issuer to use multiple-overlapping Rule 10b5–1 plans, limit the use of single-trade plans by persons other than the issuer to one such single-trade plan in any 12-month period, and add a condition that all persons entering into a Rule 10b5–1 plan must act in good faith with respect to that plan).

payments or collateral transfer—when taken in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap—would violate Rule 9j–1(a) regardless of the possession of material nonpublic information.

A person relying on the affirmative defense in adopted final Rule 9j–1(e)(1) must demonstrate that they entered into the security-based swap, or amendment, before becoming “aware of” the material nonpublic information rather than before they “came into possession” of the information, as required in re-proposed Rule 9j–1.²³⁰ The change in the rule text to an awareness standard, rather than a possession standard, brings the Rule 9j–1(e)(1) affirmative defense in line with the Commission’s intent, as described in the 2021 Proposing Release preamble.²³¹ The change also makes Rule 9j–1(e)(1) consistent with Rule 10b5–1(c)(1), which requires that the person entered into a binding contract before becoming “aware of” the material nonpublic information.²³²

b. Affirmative Defense: Policies and Procedures

Second, Rule 9j–1(e)(2) provides a defense from liability under Rules 9j–1(a)(1) through (5) for actions taken by a person, other than a natural person, who demonstrates that: (1) the individual making the investment decision on behalf of the person was not aware of the material nonpublic information; and (2) the person had implemented reasonable policies and procedures, taking into consideration the nature of the person’s business, to ensure that individuals making investment decisions would not be in violation of Rule 9j–1(a)(1) through (5).²³³ These policies and procedures may include those that restrict an individual from effecting a transaction in, or purchasing or selling, any security, including any security-based swap, as to which the individual possesses material nonpublic information, or those that prevent individuals from becoming aware of such information.²³⁴ Rule 9j–1(e)(2) is modeled on Rule 10b5–1(c)(2) and addresses concerns raised by commenters that the proposed rule would have a chilling effect on the markets. Rule 9j–1(e)(2) recognizes that

²³⁰ See 2021 Proposing Release, 87 FR at 6703.

²³¹ See 2021 Proposing Release, 87 FR at 6662.

²³² See 17 CFR 240.10b5–1(c)(1)(i)(A).

²³³ Final Rule 9j–1(e)(2).

²³⁴ See final Rule 9j–1(e)(2)(ii).

²²⁶ See final Rule 9j–1(e)(1).

²²⁷ See final Rule 9j–1(e)(1).

²²⁸ See *supra* note 212.

many market participants, such as lenders and life insurance companies, employ compliance programs which include, among other things, information barriers that prevent access to material nonpublic information by their employees who engage in security-based swap transactions for hedging or other purposes.

c. Proposed Safe Harbor: Compression

Because the Commission is adopting final Rule 9j-1(e)(2), the Commission is not adopting proposed Rule 9j-1(f)(2), which would have provided a safe harbor for transactions made in connection with certain portfolio compression exercises. The proposed safe harbor would have conflicted with Rules 10b-5 and 10b5-1 by providing the same action with protection from liability under Rule 9j-1, but not Rule 10b-5. In proposing the portfolio compression safe harbor, the Commission recognized the benefits provided by portfolio compression along with the “largely administrative nature of the portfolio compression process.”²³⁵ To be clear, the Commission continues to support portfolio compression and its benefits.²³⁶ Providing the safe harbor as proposed, however, would have sanctioned the use of material nonpublic information under Rule 9j-1, even though that use would have been prohibited by Rule 10b-5. Adopting Rule 9j-1(e)(2) instead will avoid confusion that could have resulted by treating the same conduct differently under Rules 10b-5 and 9j-1. In addition, the Rule 9j-1(e)(2) will provide security-based swap market participants the flexibility needed to engage in bilateral and multilateral portfolio compression exercises. The affirmative defense should be consistent with the manner in which Rules 10b-5 and 10b5-1(c)(2) currently apply to compression exercises and eliminates concerns that compression exercises may be more than merely administrative

and could be made on the basis of material nonpublic information.

d. Other Requested Safe Harbors and Affirmative Defenses

Certain commenters were supportive of the proposed safe harbors²³⁷ but also believed that the safe harbors were too narrow and urged the adoption of additional Rule 9j-1 safe harbors for legitimate restructuring transactions, hedging activity related to lending, transactions with counterparty disclosure regarding status as a lender and access to material nonpublic information from the borrower, multilateral amendment exercises (including ISDA protocols) or bilateral equivalents, participation in determinations committee, or for publicly executed strategies.²³⁸ One commenter raised concerns that the proposed safe harbor only addresses situations where a lender, aware of material nonpublic information, exercises rights or takes actions with respect to security-based swaps, but not if the lender exercises rights or remedies under a credit, loan, or similar agreement, while aware of material nonpublic information.²³⁹ The Commission declines to adopt additional safe harbors. The affirmative defenses the Commission is adopting provide consistency with Rule 10b5-1. Additionally, they will address concerns expressed by market participants advocating for additional safe harbors by permitting persons to enter into certain types of activity, pursuant to the requirements of the affirmative defenses, while also addressing concerns about fraud and manipulation for the entire security-based swap market.

In response to the proposed safe harbors, one commenter urged for the elimination of all safe harbors from proposed Rule 9j-1(a) liability because the Commission had “not demonstrated that a safe harbor from the prohibition on fraud and manipulation is necessary or appropriate.”²⁴⁰ This same

commenter also argued for compliance with Rule 9j-1(a) rather than for the adoption of safe harbors that it believed would encourage unlawful behavior.²⁴¹ Another commenter argued that the proposed safe harbors were overly broad and protective of actions that are inherently fraudulent.²⁴² However, as discussed above, the Commission agrees with commenters that an affirmative defense similar to those available under Rule 10b5-1 (when the investment decision is not based on material nonpublic information) is important given the similarity in the antifraud provisions. The Commission also agrees that the affirmative defenses would address concerns regarding market disruption while also addressing concerns about fraud and manipulation in the security-based swap market. Therefore, the Commission is adopting the affirmative defenses as discussed above.

In addition to the request for the inclusion of additional safe harbors and affirmative defenses, commenters also addressed the scope of Rule 9j-1 as it applies to different types of security-based swap instruments. One commenter argued for carving out sovereign debt from the scope of Rule 9j-1 due to the unlikelihood that holders of security-based swaps on sovereign debt would be able to manufacture credit events or otherwise engage in opportunistic trading, especially life insurers which are prohibited by state law from entering into speculative or abusive trading.²⁴³ While security-based swaps related to sovereign debt may present fewer opportunities for manufactured credit events or opportunistic strategies, by regulated and non-regulated market participants alike, such instruments are not without risk of fraudulent and manipulative conduct and should

²³⁵ 2021 Proposing Release, 87 FR at 6662–63 (describing the operational benefits and efficiencies resulting from portfolio compression).

²³⁶ As the Commission recognized when it adopted portfolio compression requirements for SBS Entities, there are times when entering into compression exercises would not be appropriate. See Risk Mitigation Techniques for Uncleared Security-Based Swaps, Exchange Act Release No. 87762 (Dec. 18, 2019), 85 FR 6359, at 6370 (Feb. 4, 2020) (“Risk Mitigation Adopting Release”). As a result, 17 CFR 240.15Fi-4 provides that the policies and procedures required under the rule will need to provide that portfolio compression exercises occur “when appropriate.” It would not be appropriate to enter into compression exercises when doing so would be on the basis of material nonpublic information in violation of Commission rules, including Rule 10b-5 or final Rule 9j-1.

²³⁷ Only one commenter specifically addressed the compression safe harbor of re-proposed Rule 9j-1(f)(2). See IIB-ISDA-SIFMA Letter at 11. The commenter noted that “the important operational benefits and efficiencies for market participants” supporting the safe harbor for portfolio compression exercises would also support a safe harbor for “other centralized market activities” including multilateral amendment exercises (such as an ISDA protocol) and the use of determinations committees. *Id.*

²³⁸ See Fletcher Letter at 4; IACPM Letter at 4; MFA Letter at 10–12; LSTA Letter at 8–9; IIB-ISDA-SIFMA Letter at 11–12.

²³⁹ See LSTA Letter at 8–9.

²⁴⁰ Better Markets Letter at 9. This commenter stated that it “[d]oes not appear there is any need for a safe harbor such as the one proposed by the

SEC, because it is not clear how a prohibition on fraud and manipulation could possibly apply to the performance of completely non-volitional, contractual requirements, of a contract that was entered into without fraudulent, deceptive, or manipulative intent.” *Id.* at 10. See also WebForm Comments from Anonymous Penguin, dated Oct. 7, 2022 (“Anonymous Penguin Comments”), at 1 (arguing for no affirmative defense from liability); WebForm Comments from J.T., dated Nov. 15, 2022 (“J.T. Comments”), at 1 (arguing for no safe harbor for binding contractual rights and obligations under a security-based swap).

²⁴¹ Better Markets Letter at 12 (pointing to experience with Rule 10b5-1 and citing studies and Wall Street Journal reporting).

²⁴² See WebForm Comments from Michael, dated Jan. 3, 2023 (“Michael Comments”), at 1.

²⁴³ See ACLI at 3, 13–14 (arguing that sovereign debt should be excluded from the scope of both final Rule 9j-1 and final Rule 10B-1).

remain within the scope of Rule 9j–1.²⁴⁴ One commenter supported adopting different rules for CDS as opposed to other security-based swaps due to “the structure and nature of CDS instruments,” which the commenter believes make CDS more susceptible to opportunistic strategies.²⁴⁵ However, non-CDS security-based swaps are also susceptible to fraud and manipulation and, therefore, the Commission makes no change to the scope of Rule 9j–1 to treat CDS differently from other security-based swaps. Additionally, Rule 9j–1 is tailored appropriately to address fraud and manipulation for the entire security-based swap market.

III. Rule 15Fh–4(c): Preventing Undue Influence Over Chief Compliance Officers; Policies and Procedures Regarding Compliance With Rule 9j–1 and Rule 15Fh–4(c)

A. Proposed Approach

The Commission also proposed a rule aimed at protecting the independence and objectivity of an SBS Entity’s CCO by preventing the personnel of an SBS Entity from taking actions to coerce, mislead, or otherwise interfere with the CCO. Specifically, proposed Rule 15Fh–4(c) (“proposed Rule 15Fh–4(c)”) would have made it unlawful for any officer, director, supervised person, or employee of an SBS Entity, or any person acting under such person’s direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the SBS Entity’s CCO in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.

B. Commission Action

After review of the comments, the Commission is adopting Rule 15Fh–4(c) as proposed. The final rule will protect the independence and objectivity of an SBS Entity’s CCO by preventing the

personnel of an SBS Entity from taking actions to coerce, mislead, or otherwise interfere with the CCO.

The Commission agrees with the two commenters who supported the adoption of Rule 15Fh–4(c) to further protect SBS Entities’ CCOs from undue influence.²⁴⁶ Recognizing the CCO’s critical function, one commenter believed the new rule would serve as an important deterrent to improper interference with the CCO’s duties.²⁴⁷ A second commenter supported the rule because it would reinforce existing CCO independence requirements and duties essential to effective risk management programs of SBS Entities.²⁴⁸

One commenter suggested that the proposed rule was unnecessary because the existing requirements of 17 CFR 240.15Fk–1 (“Rule 15Fk–1”) are sufficient to address the risks of undue influence on a CCO.²⁴⁹ This commenter suggested that because the CCO is required to report directly to the board of directors or senior officer of the SBS Entity, and the CCO’s compensation and removal requires approval of a majority of the SBS Entity’s board of directors, attempts by others to influence the CCO inappropriately should be unavailing.²⁵⁰ The Commission disagrees. When the Commission previously considered whether to adopt a similar requirement, it concluded that requiring a majority of the board to compensate and remove the CCO was sufficient to establish CCO independence.²⁵¹ However, in light of the rules finalized subsequent to the CCO rules, including Rule 9j–1 (which is being adopted in this release) and the risk mitigation requirements for SBS Entities,²⁵² a rule expressly prohibiting

interference with the performance of a CCO’s duties is appropriate to: (1) deter any undue influence even if not directly related to compensation or the threat of removal of the CCO; and (2) help ensure the independence and effectiveness of the CCO function.²⁵³ In connection with Rule 9j–1, as well as other rules for which the CCO is responsible, undue influence could arise from many actors (and many actions), and not merely from those actors with the power to set compensation or with hiring and firing authority over the CCO.²⁵⁴

Moreover, existing 17 CFR 240.15Fh–3(h) (“Rule 15Fh–3(h)”) requires an SBS Entity to establish and maintain a system to supervise its business and the activities of its associated persons, which must be reasonably designed to prevent violations of the provisions of applicable Federal securities laws and the rules and regulations thereunder.²⁵⁵ In addition, existing Rule 15Fk–1 requires an SBS Entity to designate a CCO, who must comply with certain duties. Such duties include “[t]ak[ing] reasonable steps to ensure that the [SBS Entity] establishes, maintains and reviews written policies and procedures reasonably designed to achieve compliance with the [Exchange Act] and the rules and regulations thereunder relating to its business as [an SBS Entity].”²⁵⁶ Failure to establish, maintain, and review written policies and procedures reasonably designed to

²⁵³ As the Commission explained when adopting similar rules prohibiting persons from unduly influencing auditors pursuant to section 303(a) of the Sarbanes Oxley Act of 2002 (“Sarbanes-Oxley Act”), activities by persons acting “under the direction” of officers and directors of the issuer “currently may constitute violations of the anti-fraud or other provisions of the securities laws or aiding or abetting or causing an issuer’s violations of the securities laws.” Improper Influence on Conduct of Audits, Exchange Act Release No. 47890 (May 20, 2003), 68 FR 31820, 31821 (May 28, 2003) (internal citations omitted). Nevertheless, like the rule implementing section 303(a) of the Sarbanes-Oxley Act, Rule 15Fh–4(c) would provide the Commission with an additional means of addressing efforts by persons acting under the direction of an officer or director to thwart the responsibilities of the CCO. See also Compliance Programs of Investment Companies and Investment Advisers, Investment Advisers Act Release No. 2204 (Dec. 17, 2003), 68 FR 74714, 74721–22 (Dec. 24, 2003).

²⁵⁴ For example, an employee at an SBS Entity planning an opportunistic strategy could attempt to mislead the CCO by submitting false documentation to the CCO in order to avoid disclosing the build-up of a large position that might require public reporting and thwart the plans of the employee.

²⁵⁵ See 17 CFR 240.15Fh–3(h).

²⁵⁶ See 17 CFR 240.15Fk–1. Additionally, in its application for registration, an SBS Entity is required to include a senior officer’s certification that the SBS Entity has developed and implemented written policies and procedures reasonably designed to prevent violation of Federal securities laws and the rules thereunder. See 17 CFR 240.15Fb2–1(b).

²⁴⁴ As of Nov. 25, 2022, sovereign CDS have the second highest gross notional amount outstanding among credit security-based swaps. See *infra* section V.C.2, Table 1. The Commission further observes that the share of CDS written on sovereign debt has risen from less than four percent of the total notional amounts outstanding in the global CDS market in 2007 to 14 percent at the end of 2020. For single-name CDS during that same period, the share of the sovereign sector grew from six percent to close to one-third. See Antulio N. Bomfim, “Credit Default Swaps,” Finance and Economics Discussion Series 2022–023 at 4, Washington: Board of Governors of the Federal Reserve System (2022), available at <https://doi.org/10.17016/FEDS.2022.023>. See also Ben St. Clair, “Pimco Loses \$400m on Failed Russia CDS Bets,” Risk.Net (June 20, 2022) (describing the effects on CDS of Russia’s failure to pay additional interest due on its sovereign bonds in Apr. 2022).

²⁴⁵ See Fletcher Letter at 4.

²⁴⁶ See Better Markets Letter at 14; Letter from Patrick T. Campbell, New York City Bar Association, dated Mar. 21, 2022 (“NYC Bar Letter”).

²⁴⁷ See Better Markets Letter at 14.

²⁴⁸ See NYC Bar Letter at 2–5.

²⁴⁹ See Letter from Stephanie Webster, IIB, Chris Young, ISDA, and Kyle Brandon, SIFMA, dated Mar. 21, 2022 (“IIB-ISDA-SIFMA CCO Letter”), at 3.

²⁵⁰ *Id.*

²⁵¹ The Commission considered and rejected a prohibition on attempts by officers, directors, or employees to coerce, mislead, or otherwise mislead the CCO when it adopted business conduct standards for SBS Entities in 2016. See Business Conduct Standards Adopting Release, 81 FR at 30054–55. That rulemaking included, among other things, a rule to require an SBS Entity to designate a CCO and impose certain duties and responsibilities on that CCO, as well as antifraud provisions for SBS Entities. See 17 CFR 240.15Fk–1; 240.15Fh–4(a).

²⁵² Risk mitigation rules are designed to further effective risk management by requiring the existence of sound documentation, periodic reconciliation of portfolios, rigorously tested valuation methodologies, and sound collateralization practices. See Risk Mitigation Adopting Release, 85 FR at 6390–91.

achieve compliance with the Exchange Act and the rules and regulations thereunder (including Rules 9j–1 and 15fh–4(c)) may result in violations by the SBS Entity of Rule 15Fh–3(h), as well as Rule 15Fk–1.²⁵⁷ Rule 15fh–4(c) protects investors and promotes the fairness of the markets by supporting the ability of CCOs to meet their important obligations to foster compliance without undue influence, which should ultimately support the integrity of SBS Entities and the markets.

One commenter argued that the scope of proposed Rule 15Fh–4(c) was “unclear and could lead to confusion and uncertainty in the market as to which activities are prohibited.”²⁵⁸ This commenter went on to suggest that, if the Commission did adopt Rule 15fh–4(c), the final rule should clarify which activities are prohibited by including materiality and intent standards that would limit the prohibited interference to knowingly making untrue statements or omitting material facts.²⁵⁹ The commenter believed that ambiguities could have a chilling effect on communications between the CCO and personnel of the SBS Entity.²⁶⁰

After considering the comments, the Commission declines to revise Rule 15fh–4(c) and adopts the rule as proposed. Rule 15fh–4(c) protects the independence and objectivity of an SBS Entity’s CCO by prohibiting undue influence by other personnel. The concerns regarding the rule having a chilling effect on communications are misplaced since the rule prohibits actions to coerce, manipulate, mislead, or fraudulently influence CCOs—not good faith disagreements or legitimate discussions. However, such influence could take many forms and is not limited to material misstatements or omissions. As noted, the Commission has adopted the majority of its Title VII rules related to security-based swaps,²⁶¹ including rules relating to trading relationship documentation, dispute resolution, portfolio reconciliation, or portfolio compression (“Risk Mitigation

Rules”). As the Commission explained when adopting the Risk Mitigation Rules, those rules were designed to further effective risk management by requiring the existence of sound documentation, periodic reconciliation of portfolios, rigorously tested valuation methodologies, and sound collateralization practices.²⁶² Attempts by officers, directors, or employees to hide transactions, submit false valuations, or manipulate or fraudulently influence the CCO in the performance of their duties related to the Risk Mitigation Rules would undermine the SBS Entity’s risk management and could pose risk to the market. Therefore, the Commission is adopting a rule that is broad enough to apply to these actions and any others that may undermine the independence and responsibilities of the CCO.

A commenter also argued for more clarity with regard to the intent and conduct required to be liable under Rule 15fh–4(c).²⁶³ The Commission declines to make any revisions to the proposed rule in response to this comment. Specifically, the acts to “coerce, manipulate, mislead, or fraudulently influence” that would be prohibited by Rule 15fh–4(c) imply compelling the CCO to act in a certain way through pressure, threats, trickery, intimidation, misrepresentation, or some other form of purposeful action not limited to untrue statements or omissions of material facts, and therefore, further clarity is not necessary.²⁶⁴ As noted, one of the purposes of Title VII security-based swap legislation is promoting the integrity of the security-based swap market. Such a purpose would not be served by imposing a scienter or materiality requirement on Rule 15fh–4(c) violations. Further, the Commission believes that the rule will encourage directors, officers, supervised persons, or employees of SBS Entities to exercise reasonable attention and care in their dealings with CCOs.

One commenter suggested expanding the scope of the rule to actions taken to coerce, manipulate, mislead, or fraudulently influence all officers and other decision-makers, and not limit the rule to actions taken with respect to the SBS Entity’s CCO.²⁶⁵ However,

activities taken by persons under the direction of officers and directors of an issuer may already constitute violations of the securities laws.²⁶⁶ This additional rule is appropriate given the key role that the CCO plays in an SBS Entity’s compliance with the security-based swap related regulations, such as the risk mitigation requirements for SBS Entities. Furthermore, it provides an additional means of addressing efforts by persons acting under the direction of an officer or director to thwart the responsibilities of the CCO.

IV. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (“PRA”)²⁶⁷ imposes certain requirements on Federal agencies in connection with the conducting or sponsoring of any “collection of information.”²⁶⁸ Neither Rule 9j–1 nor Rule 15fh–4(c) contain a collection of information requirement within the meaning of the PRA. Specifically, Rule 9j–1 contains prohibitions designed to prevent fraud, manipulation, and deception in connection with effecting transactions in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap. Rule 15fh–4(c) generally makes it unlawful for certain specified persons to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence an SBS Entity’s CCO in the performance of their duties under the Federal securities laws or the rules and regulations thereunder. Neither of those rules require a person to establish, maintain, and enforce written policies and procedures reasonably designed to ensure compliance with the applicable rule. However, to the extent that a person is already subject to a similar policies and procedures requirement, any updates to those policies and procedures would likely be captured by an existing collection of information. For example, as previously explained, Rule 15Fh–3(h) requires an SBS Entity to establish and maintain a system to supervise its business and the activities of its associated persons and that system must be reasonably designed to prevent violations of the provisions of applicable Federal securities laws and the rules and regulations thereunder. In the PRA analysis when that rule was adopted, the Commission estimated that each SBS Entity would spend 60 hours per year to update each of the policies and procedures required by Rule 15Fh–

²⁵⁷ The SBS Entity could also face liability under 17 CFR 240.15Fb2–1(b) and (h) under such circumstances.

²⁵⁸ IIB–ISDA–SIFMA CCO Letter at 1.

²⁵⁹ See *id.* at 2 (stating that the rule is unclear and could lead to confusion and uncertainty in the market as to which activities are prohibited and that the rule does not provide any materiality or intent standards, which could allow for immaterial or inadvertent actions or statements to result in liability).

²⁶⁰ *Id.* IIB–ISDA–SIFMA was concerned that questions could arise as to whether good faith disagreements or legitimate discussions “involve[d] ‘interference’ with or ‘undue influence’ over a CCO.” *Id.*

²⁶¹ See *supra* note 16.

²⁶² See Risk Mitigation Adopting Release, 85 FR at 6390–91.

²⁶³ See IIB–ISDA–SIFMA CCO Letter at 2.

²⁶⁴ The Commission came to a similar conclusion when adopting similar rules prohibiting persons from unduly influencing auditors pursuant to section 303(a) of the Sarbanes Oxley Act of 2002 (“Sarbanes-Oxley Act”). See *Improper Influence on Conduct of Audits*, Exchange Act Release No. 47890 (May 20, 2003), 68 FR 31820, 31823 (May 28, 2003).

²⁶⁵ Michael Comments at 1.

²⁶⁶ See *supra* note 252.

²⁶⁷ 44 U.S.C. 3501 *et seq.*

²⁶⁸ See 44 U.S.C. 3502(3).

3.²⁶⁹ Both Rule 9j–1 and Rule 15fh–4(c) are intended solely to identify actions that an SBS Entity is not permitted to take, and as such do not make substantive modifications to any existing collection of information or impose new information collection requirements within the meaning of the PRA. Accordingly, we are not revising any burden and cost estimates in connection with these amendments.

V. Economic Analysis

A. Introduction

The Commission is mindful of the economic effects, including the costs and benefits, of Rule 9j–1 and Rule 15fh–4(c). Section 3(f) of the Exchange Act²⁷⁰ directs the Commission, when engaging in rulemaking where it is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. In addition, section 23(a)(2) of the Exchange Act²⁷¹ requires the Commission, when making rules under the Exchange Act, to consider the impact that the rules would have on competition, and prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

The analysis below addresses the likely economic effects of Rule 9j–1 and Rule 15fh–4(c), including the anticipated benefits and costs of the rules and their likely effects on efficiency, competition, and capital formation. Many of the benefits and costs discussed below are difficult to quantify. For example, the Commission cannot quantify the impact of litigation and litigation risk on counterparties and underlying entities or the overall impact on the credibility and reputation of the security-based swap market. The extent of some of these impacts will depend, in part, on events difficult to predict that might affect security-based swaps, such as changes in counterparty or reference underlying entity behavior. Reputational and credibility effects also are difficult to measure. Therefore, while the Commission attempted to quantify economic effects where possible, much of the discussion of the anticipated economic effects below is qualitative and descriptive in nature.

The Commission received a number of comments related to various aspects of the economic analysis of re-proposed Rule 9j–1 and proposed Rule 15Fh–4(c). The Commission has considered and responded to these comments in the sections that follow.

B. Broad Economic Considerations

This section discusses certain aspects of the security-based swap market that may raise concerns or may be associated with concerns that would be addressed by final Rule 9j–1. The discussion is illustrative and is not intended to exhaust all types of conduct that may implicate final Rule 9j–1.

Opportunistic Strategies

Opportunistic strategies often involve CDS buyers or sellers taking steps, either with or without the participation of the underlying entity, to avoid, trigger, delay, accelerate, decrease, and/or increase payouts on CDS.²⁷² When market participants employ one of these strategies, they intend to obtain gains from the positions they hold that go beyond those corresponding to the initial profit and loss expectation (the initial payoff function) at trade execution. This additional gain would be obtained to the direct detriment of a counterparty that is unaware of that additional loss potential.²⁷³ One commenter pointed out that while CDS have many privately and socially valuable uses, such instruments could lend themselves to abuses such as opportunistic strategies.²⁷⁴

To the extent that market participants anticipate opportunistic strategies, the CDS spread or price becomes a reflection of the likelihood of an opportunistic strategy being announced (or, if already announced, of succeeding) and decouples from the credit fundamentals of the reference entity.²⁷⁵ This effect reduces the utility of the CDS market as a venue to offload or take on the credit risk of a company because prices no longer reflect credit risk; bona fide hedgers or speculators in this market would be more likely to exit,

as they cannot readily “trade” the credit of a company.²⁷⁶ In addition to their adverse impact on price efficiency, opportunistic strategies may impair the liquidity of the CDS markets. The fact that a counterparty might manufacture or delay a credit event in the future can deter others from entering into such contracts. If fewer parties enter into CDS contracts, the overall value of CDS as a risk-transferring instrument for the market will be reduced.²⁷⁷ Two commenters suggested that lenders may demand a higher rate of return (cost of debt) on new debt issuances by a reference entity that was involved in a manufactured credit event to compensate for the risk that such manufactured events may recur in the future.²⁷⁸

C. Baseline

1. Existing Regulatory Frameworks

As discussed in section I.A, because security-based swaps are included in the Exchange Act’s definition of “security,” participants in the security-based swap market are currently subject to the general antifraud and anti-manipulation provisions of the Federal securities laws, including sections 9(a) and 10(b) of the Exchange Act, and Rule 10b–5 thereunder, and section 17(a) of the Securities Act. In particular, Rule 10b5–1 provides that a person trades “on the basis of” material nonpublic information when the person purchases or sells securities while aware of the information. However, the rule also sets forth several affirmative defenses to permit persons to trade in certain circumstances where it is clear that the information was not a factor in the decision to trade.²⁷⁹ Several commenters pointed out that most security-based market participants have organized their business activities and implemented policies and procedures to allow them to rely on the affirmative defense provided by Rule 10b5–1(c)(2) from liability under Rule 10b–5.²⁸⁰

²⁷⁶ See Gina-Gail S. Fletcher, *Engineered Credit Default Swaps: Innovative or Manipulative?*, 94 N.Y.U. L. Rev. 1073 (2019) (explaining that “engineered” or “manufactured” transactions distort the information reflected in CDS spreads, to the point where the default risk expressed in CDS spreads is no longer connected to the financial condition of the underlying entity).

²⁷⁷ See Fletcher Letter at 3.

²⁷⁸ See AFRED Letter at 4; Fletcher Letter at 3.

²⁷⁹ See Selective Disclosure and Insider Trading, Exchange Act Release No. 43154 (Aug. 15, 2000), 65 FR 51716 (Aug. 24, 2000).

²⁸⁰ See IACPM Letter at 4; IIB-ISDA–SIFMA Letter at 4–5; MFA Letter at 13; SIFMA AMG Letter at 11. See also *supra* section I.E.2. EBF supports the arguments in the IIB-ISDA–SIFMA Letter regarding proposed Rule 9j–1. See Letter from EBF at 1; *supra* note 124.

²⁶⁹ See Business Conduct Standards Adopting Release, 81 FR at 30094.

²⁷⁰ 15 U.S.C. 78c(f).

²⁷¹ 15 U.S.C. 78w(a)(2).

²⁷² See *supra* note 35 and accompanying text for a discussion of the settlement process that determines payout on a CDS contract that relies on the ISDA standard documentation.

²⁷³ The market participant’s gain from the transaction is inversely proportional to the gain of the counterparty, so the larger the market participant’s position (and gain), the larger the counterparty’s loss.

²⁷⁴ Letter from Henry T.C. Hu, dated Mar. 21, 2022, at 6.

²⁷⁵ Two commenters noted that opportunistic strategies impede price efficiency in the CDS market, particularly the CDS of distressed issuers because such strategies can be more profitable when implemented on distressed issuers. See AFRED Letter at 4–5; Fletcher Letter at 3.

In addition, the Dodd-Frank Act expanded the anti-manipulation provisions of section 9 of the Exchange Act to encompass security-based swap transactions and required the Commission to adopt rules to prevent fraud, manipulation, and deception in connection with security-based swaps.²⁸¹ The Commission has now finalized a majority of its Title VII rules related to SBS Entities, including rules that allow such persons to manage the market, counterparty, operational, and legal risks associated with their security-based swap business. These include the Risk Mitigation Rules;²⁸² rules relating to capital, margin, and segregation requirements for SBSDs, MSBSPs, and broker-dealers;²⁸³ and rules relating to recordkeeping and reporting requirements for SBSDs, MSBSPs, and broker-dealers.²⁸⁴ These rules are discussed in the 2021 Proposing Release.²⁸⁵ As discussed earlier, the CFTC has largely completed its Title VII rulemakings related to swaps, including the adoption of antifraud and anti-manipulation rules.²⁸⁶

Finally, Rule 15Fk-1 requires an SBS Entity to designate a CCO and imposes certain duties and responsibilities on that CCO.²⁸⁷ Additionally, the rule requires that a majority of the board approve the compensation and removal of the CCO.²⁸⁸ Rule 15Fh-4(a) makes it unlawful for an SBS Entity to: (1) employ any device, scheme, or artifice to defraud any special entity or prospective customer who is a special entity; (2) engage in any transaction, practice, or course of business that operates as a fraud or deceit on any special entity or prospective customer who is a special entity; or (3) engage in any act, practice, or course of business that is fraudulent, deceptive, or manipulative.²⁸⁹ Further, existing Rule 15Fh-3(h) requires an SBS Entity to establish and maintain a system to supervise its business and the activities of its associated persons; the system

must be reasonably designed to prevent violations of the provisions of applicable Federal securities laws and the rules and regulations thereunder.²⁹⁰

2. Security-Based Swap Data, Market Participants, Dealing Structures, and Levels of Security-Based Swap Trading Activity

As of January 4, 2023, there were 50 entities registered with the Commission as SBSDs, and no entities registered as MSBSPs.²⁹¹ Market participants such as SBSDs and MSBSPs were required to report security-based swap transactions to registered security-based swap data repositories (“SBSDRs”) pursuant to Regulation SBSR beginning on November 8, 2021.

The Commission uses information reported pursuant to Regulation SBSR to two registered SBSDRs—Depository Trust & Clearing Corporation Data Repository (“DDR”) and the ICE Trade Vault (“ITV”)—to describe the baseline.²⁹² Table 1 shows that U.S. security-based swap market activity is split across three asset classes: credit, equity, and interest rate. Based on information reported to DDR, as of November 25, 2022, there were approximately 523,000, 3.4 million, and 5,700 active security-based swaps in the credit, equity, and interest rate asset classes, respectively. The gross notional amounts outstanding in the credit, equity, and interest rate asset classes were respectively, approximately \$2.8, \$3.6, and \$0.18 trillion.²⁹³ Based on

information reported to ITV, as of November 25, 2022, there were approximately 155,000 active credit security-based swaps with gross notional amount outstanding of approximately \$1.9 trillion.

Table 1 also shows that U.S. security-based swap market participants trade a variety of security-based swaps in each of the three asset classes. Based on information reported to DDR, as of November 25, 2022, active credit security-based swaps fall into five product types. Single-name corporate CDS constitute the largest product type, with approximately 364,000 active CDS and \$1.6 trillion gross notional amount outstanding. The second largest active credit security-based swaps product type consists of single-name sovereign CDS, with approximately 94,000 active CDS and \$0.9 trillion gross notional amount outstanding. For active equity security-based swaps, equity portfolio swaps constitute the largest product type, with approximately 2.3 million active equity portfolio swaps and \$1.7 trillion gross notional amount outstanding. The second largest active equity security-based swaps product type consists of equity swaps, with approximately 492,000 active equity swaps and \$1.2 trillion gross notional amount outstanding. Equity portfolio swaps and equity swaps can be further divided into sub-products that include, among other things, equity TRS.²⁹⁴ In the interest rate asset class, exotics constitute the largest product type, with approximately \$0.1 trillion gross notional amount and 4,400 active exotic swaps outstanding. Based on information reported to ITV, as of November 25, 2022, active credit security-based swaps fall into two

²⁹⁰ See 17 CFR 240.15Fh-3(h).

²⁹¹ See List of Registered Security-Based Swap Dealers and Major Security-Based Swap Participants, available at https://www.sec.gov/files/list_of_sbsds_msbps_1_4_2023locked_final.xlsx (providing the list of registered SBSDs and MSBSPs that was updated as of Jan. 4, 2023).

²⁹² DDR operates as a registered SBSDR for security-based swap transactions in the credit, equity, and interest rate derivatives asset classes. ITV operates as a registered SBSDR for security-based swap transactions in the credit derivatives asset class. See Security-Based Swap Data Repositories; DTCC Data Repository (U.S.) LLC; Order Approving Application for Registration as a Security-Based Swap Data Repository, Exchange Act Release No. 91798 (May 7, 2021), 86 FR 26115 (May 12, 2021); Security-Based Swap Data Repositories; ICE Trade Vault, LLC; Order Approving Application for Registration as a Security-Based Swap Data Repository, Exchange Act Release No. 92189 (June 16, 2021), 86 FR 32703 (June 22, 2021). The statistics presented herein are based on the SBS Report. See *supra* note 42.

²⁹³ Active security-based swaps are those that have been neither terminated nor reached their scheduled maturity and are therefore open positions as of Nov. 25, 2022. Gross notional amount outstanding represents the total outstanding notional value of active, market-facing security-based swaps on Nov. 25, 2022. Security-based swaps are considered to be “market-facing” when they are executed at arms-length between third parties. While a reporting party is only required to report a transaction to one SBSDR—either DDR or

ITV—some uncleared security-based swaps in DDR also appear in ITV. This overlap is very limited in scope. As of Nov. 25, 2022, there were 605 active credit security-based swaps in ITV that were reported as uncleared (0.4% of the 154,903 active credit security-based swaps in ITV). The 605 active credit security-based swaps had a gross notional outstanding of \$4.73 billion (0.3% of the approximately \$1,900 billion gross notional outstanding of all active credit security-based swaps in ITV). These statistics provide an upper bound of the overlap between ITV and DDR and indicate that the overlap is very limited in scope. See SBS Report at 4 and 10.

²⁹⁴ An equity swap references a single underlier while an equity portfolio swap involves a portfolio wrapper under which multiple swaps can be traded with operational efficiency. See *Central Clearing in the Equity Derivatives Market: An ISDA Study*, ISDA.org (June 2014) at 10, available at <https://www.isda.org/a/6PDDE/central-clearing-in-the-egd-market-final.pdf>. See ISDA, ISDA Taxonomy 2.0—Finalized, ISDA.org (Sep. 4, 2019), available at https://www.isda.org/a/o1MTE/ISDA-Taxonomy-EQ-CR-FX-IR_v2.0_3-September_2019-FINAL.xls (indicating that equity portfolio swaps and equity swaps can be further divided into sub-products that include, among other things, equity TRS).

²⁸¹ See *supra* note 4 and accompanying text.

²⁸² See *supra* section III.B and note 262.

²⁸³ See Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital and Segregation Requirements for Broker-Dealers, Exchange Act Release No. 86175 (June 21, 2019), 84 FR 43872 (Aug. 22, 2019).

²⁸⁴ See Recordkeeping and Reporting Requirements for Security-Based Swap Dealers, Major Security-Based Swap Participants, and Broker-Dealers, Exchange Act Release No. 87005 (Sep. 19, 2019), 84 FR 68550 (Dec. 16, 2019).

²⁸⁵ See 2021 Proposing Release, 87 FR at 6681–82.

²⁸⁶ See *supra* note 16.

²⁸⁷ See 17 CFR 240.15Fk-1(a) through (c).

²⁸⁸ See 17 CFR 240.15Fk-1(d).

²⁸⁹ See 17 CFR 240.15Fh-4(a).

product types. Single-name corporate CDS constitute the largest product type, with approximately 135,000 active CDS and \$1.3 trillion gross notional amount

outstanding. The second largest active credit security-based swaps product type consists of single-name sovereign CDS, with approximately 20,000 active

CDS and \$0.5 trillion gross notional amount outstanding.

TABLE 1—GROSS NOTIONAL AMOUNT AND ACTIVE SECURITY-BASED SWAPS OUTSTANDING ON NOV. 25, 2022, CATEGORIZED BY ASSET CLASS AND PRODUCT CLASSIFICATION ^a

SBSDR	Asset class	Product type	Gross notional amount outstanding (millions of USD)	Active security-based swap count
DDR	Credit	Index	44,407	2,992
		Single-Name: Corporate	1,556,315	364,465
		Single-Name: Sovereign	900,072	93,807
		TRS ^b	156,849	49,867
		Other ^c	122,970	12,081
	Equity	Total	2,780,613	523,212
		Portfolio Swap	1,688,672	2,266,706
		Swap	1,183,279	491,508
		Contract For Difference	398,952	642,965
		Option	6,915	1,281
		Forward	5,663	1,393
		Other ^d	330,136	41,115
		Total	3,613,617	3,444,968
	Interest Rate	Exotic	153,306	4,419
		Forward	23,818	1,164
		Other ^e	868	122
ITV	Credit	Total	177,992	5,705
		Single-Name: Corporate	1,348,002	134,741
		Single-Name: Sovereign	544,414	20,162
		Total	1,892,416	154,903

^aFor cleared security-based swaps in DDR, this table incorporates only one of the two security-based swaps that result from the clearing process. For ITV, this table incorporates all of the cleared security-based swaps.

^bAs a general matter, TRS include non-CDS debt-based security swaps, equity-based security swaps, and mixed swaps. Counterparties in the TRS market use the contracts to obtain exposure, usually leveraged, to the total economic performance of a security or index and benefit from not having to own the security itself. Market participants, such as mutual funds, hedge funds, and endowments, use TRS to obtain exposure in markets where they would face difficulties purchasing or selling the underlying security (e.g., a market participant may find it difficult to buy a foreign company's security or locate a security to sell short) while taking advantage of the capital efficiencies of not holding the security in their inventories. *See also supra* section I.B.1, which discusses the ongoing payment stream of TRS, among other things.

^cIncludes the following products reported to SBSDRs: exotic, index tranche, swaptions, and other single-name (e.g., asset-backed, loan, and municipal security-based swaps).

^d"Other" is a category in the DDR Equity Product ID field. All Product ID categories are listed in the table.

^eIncludes the following products reported to SBSDRs: inflation, debt option, and cross-currency.

Table 2 shows that both SBS Entities and non-SBS Entities participate in all three asset classes in the U.S. security-based swap market. Based on information reported to DDR, as of November 25, 2022, SBS Entities and non-SBS Entities had, respectively, entered into approximately 813,000 and 234,000 active credit security-based swaps.²⁹⁵ The gross notional amounts outstanding of the active credit security-based swaps held by SBS Entities and non-SBS Entities were, respectively, approximately \$4.4 and \$1.2 trillion. In the equity asset class, SBS Entities and

non-SBS Entities had, respectively, entered into approximately 4.0 million and 2.9 million active equity security-based swaps. The gross notional amounts outstanding of the active equity security-based swaps held by SBS Entities and non-SBS Entities were, respectively, approximately \$4.5 and \$2.7 trillion. In the interest rate asset class, SBS Entities and non-SBS Entities had, respectively, entered into approximately 6,200 and 5,200 active interest rate security-based swaps. The gross notional amounts outstanding of the active interest rate security-based

swaps held by SBS Entities and non-SBS Entities were, respectively, approximately \$0.2 and \$0.1 trillion. Based on information reported to ITV, as of November 25, 2022, SBS Entities and non-SBS Entities had, respectively, entered into approximately 123,000 and 33,000 active credit security-based swaps. The gross notional amounts outstanding of the active credit security-based swaps held by SBS Entities and non-SBS Entities were, respectively, approximately \$1.6 and \$0.3 trillion.

²⁹⁵ For cleared security-based swaps where at least one counterparty is an SBS Entity, Table 2 reflects the security-based swaps entered into by

each of the original counterparties, but does not include the positions of the clearing organizations themselves. For uncleared security-based swaps,

Table 2 reflects the security-based swaps entered into by each of the original counterparties. *See* SBS Report at 5.

TABLE 2—GROSS NOTIONAL AMOUNT AND ACTIVE SECURITY-BASED SWAPS OUTSTANDING ON NOV. 25, 2022, CATEGORIZED BY ASSET CLASS AND REGISTRANT TYPE ^a

SBSDR	Asset class	Registrant type	Gross notional amount outstanding (millions of USD)	Active security-based swap count
DDR	Credit	Total	5,561,226	1,046,424
		SBS Entities	4,403,130	812,647
		Other	1,158,096	233,777
	Equity	Total	7,227,234	6,889,936
		SBS Entities	4,490,592	4,013,393
		Other	2,736,642	2,876,543
	Interest Rate	Total	355,984	11,410
		SBS Entities	210,663	6,214
		Other	145,321	5,196
ITV	Credit	Total	1,897,249	155,578
		SBS Entities	1,632,251	122,831
		Other	264,998	32,747

^aFor cleared security-based swaps where at least one counterparty is an SBS Entity, Table 2 reflects the security-based swaps entered into by each of the original counterparties, but does not include the positions of the clearing organizations themselves. For uncleared security-based swaps, Table 2 reflects the security-based swaps entered into by each of the original counterparties.

In addition to information reported to registered SBSDRs, the Commission also uses data from the DTCC Derivatives Repository Limited Trade Information Warehouse (“DTCC-TIW”) to describe the baseline. DTCC-TIW provides data regarding the activity of market participants in the single-name CDS market during the period from 2006 to the end of 2021.²⁹⁶ The Commission acknowledges that limitations in the data constrain the extent to which it is possible to quantitatively characterize the security-based swap market.²⁹⁷ Based on an analysis of DTCC-TIW data, staff concluded that there are 2,326 transacting agents that engaged directly in trading between November 2006 and December 2021 with 15,721 accounts.²⁹⁸

²⁹⁶ DTCC-TIW provides weekly positions and monthly transaction files on a voluntary basis for single-name and index-based CDS. These data cover all positions and transactions where one of the counterparties is a U.S. entity or the reference entity is a U.S. entity, with status as a U.S. entity determined by DTCC-TIW. In DTCC-TIW, the Commission observes end of week CDS positions for all U.S. entities, foreign counterparties to a U.S. entity, or foreign counterparties trading a CDS referencing a U.S. underlying entity. The DTCC-TIW data have limitations. The data do not address two foreign counterparties with CDS referencing foreign underlying entities. In addition, the DTCC-TIW data do not provide any intra-weekly CDS position information, nor any information on the underlying security holdings of reference entities. Further, DTCC-TIW is a voluntary database where market participants on a voluntary basis submit transactions and end of week holdings.

²⁹⁷ The Commission also relies on qualitative information regarding market structure and evolving market practices provided by commenters and the knowledge and expertise of Commission staff.

²⁹⁸ These 2,326 entities, which are presented in more detail in Table 3, below, include all DTCC-TIW-defined “firms” shown in DTCC-TIW as transaction counterparties that report at least one transaction to DTCC-TIW as of Dec. 2021. The staff in the Division of Economic and Risk Analysis classified these firms by machine-matching names

Data from the DTCC-TIW show that activity in the single-name CDS market is concentrated among a relatively small number of entities, predominantly registered SBSDRs.²⁹⁹ The top two SBSDRs (when accounts are sorted by number of counterparties) each transacted with over a thousand counterparty accounts, consisting of both other SBSDRs and non-SBSDRs. The next 13 percent of SBSDRs each transacted with 500 to 1,000 counterparty accounts; the following 21 percent of SBSDRs each transacted with

to known third-party databases and by manual classification. See, e.g., Security-Based Swap Transactions Connected with a Non-U.S. Person’s Dealing Activity That Are Arranged, Negotiated, or Executed By Personnel Located in a U.S. Branch or Office or in a U.S. Branch or Office of an Agent; Security-Based Swap Dealer De Minimis Exception, Exchange Act Release No. 77104 (Feb. 10, 2016), 81 FR 8598, 8602 n.43 (Feb. 19, 2016). Manual classification was based in part on searches of the EDGAR and Bloomberg databases, the SEC’s Investment Adviser Public Disclosure database, and a firm’s public website or the public website of the account represented by a firm. As mentioned above, data on CDS market participants come from DTCC-TIW. Principal holders of CDS risk exposure are represented by “accounts” in the DTCC-TIW. “Accounts” as defined in the DTCC-TIW context are not equivalent to “accounts” in the definition of “U.S. person” provided by Exchange Act Rule 3a71-3(a)(4)(i)(C). 17 CFR 3a71-3(a)(4)(i)(C). One entity or legal person (known as “transacting agent” in the terminology of DTCC-TIW) may have multiple accounts. For example, a bank that is a transacting agent may have one DTCC-TIW account for its U.S. headquarters and one DTCC-TIW account for one of its foreign branches.

²⁹⁹ Dealers are generally persons engaged in the business of buying and selling securities for their own account, through a broker or otherwise. 15 U.S.C. 78c(a)(5). SBSDRs are generally defined as persons who hold themselves out as dealers in security-based swaps; make markets in security-based swaps; regularly enter into security-based swaps as an ordinary course of business for their own account; or engage in any activity causing them to be commonly known in the trade as a dealer or market maker in security-based swaps. 17 CFR 240.3a71-1.

100 to 500 counterparty accounts; and 62 percent of SBSDRs each transacted security-based swaps with fewer than 100 counterparty accounts in 2021. The median number of counterparty accounts across SBSDRs is 16 (the mean is approximately 191). SBSDR-intermediated transactions reached a gross notional amount of approximately \$1.5 trillion, approximately 66 percent of which was intermediated by the top five SBSDR accounts. The median non-dealer counterparty transacted with only one SBSDR account (with an average of approximately 1.9 SBSDR accounts) in 2021.

Non-dealer single-name CDS market participants include, but are not limited to, investment companies, pension funds, private funds, sovereign entities, and industrial companies. We observe that most non-dealer market participants of single-name CDS do not engage directly in the trading of security-based swaps, but trade through banks, investment advisers or funds, or other types of firms, which we refer to as transacting agents, consistent with DTCC-TIW terminology.³⁰⁰ As shown in Table 3, close to 79 percent of transacting agents are identified as investment advisers or funds.³⁰¹ Although investment advisers and funds are the vast majority of transacting

³⁰⁰ Transacting agents participate directly in the security-based swap market, without relying on an intermediary, on behalf of their principals, investment companies, pension funds, private funds, sovereign entities, and industrial companies. For example, a university endowment may hold a position in a security-based swap that is established by an investment adviser that transacts on the endowment’s behalf. In this case, the university endowment is a principal that uses the investment adviser as its transacting agent.

³⁰¹ DTCC-defined “firms” shown in DTCC-TIW, which we refer to here as “transacting agents.”

agents, the transactions they executed account for only about 15 percent of all single-name CDS trading activity

reported to the DTCC–TIW, measured by the number of transaction sides.³⁰² The vast majority of transactions,

approximately 82 percent, measured by number of transaction-sides were executed by ISDA-recognized dealers.

TABLE 3—THE NUMBER OF TRANSACTING AGENTS BY COUNTERPARTY TYPE AND THE FRACTION OF TOTAL TRADING ACTIVITY, FROM NOV. 2006 THROUGH DEC. 2021, REPRESENTED BY EACH COUNTERPARTY TYPE

Transacting agents	Number	Percent	Transaction share (%)
Investment Advisers/Funds ^a	1,858	78.7	14.6
Banks (excluding G16) ^b	278	11.8	3.3
Pension Funds	30	1.3	0.1
Insurance Companies	49	2.1	0.2
ISDA-Recognized Dealers ^c	17	0.7	81.6
Other	130	5.5	0.2
Total	2,362	100.0	100

^a Investment Adviser/Funds—For purposes of this table, these entities have the following characteristics: clients are predominantly individuals, institutions, and investment companies that take public and institutional money. Some also manage pooled investment vehicles (*e.g.*, hedge funds), private equity and venture capital.

^b Banks (excluding G16)—The primary characteristic is the entity is trading for its own account and not just on behalf of its clients. This includes depository institutions, swap dealers (market makers), and classically-defined investment banks.

^c ISDA recognized dealer—Market makers (dealers) identified by ISDA as belonging to the G14 or G16 dealer group during the period. *See, e.g.*, 2010 ISDA Operations Benchmarking Survey (2010), available at <https://www.isda.org/a/5eiDE/isda-operations-survey-2010.pdf>.

Figure 1 describes the percentage of global, notional transaction volume in North American corporate single-name CDS reported to the DTCC–TIW from January 2011 through December 2021, separated by whether transactions are

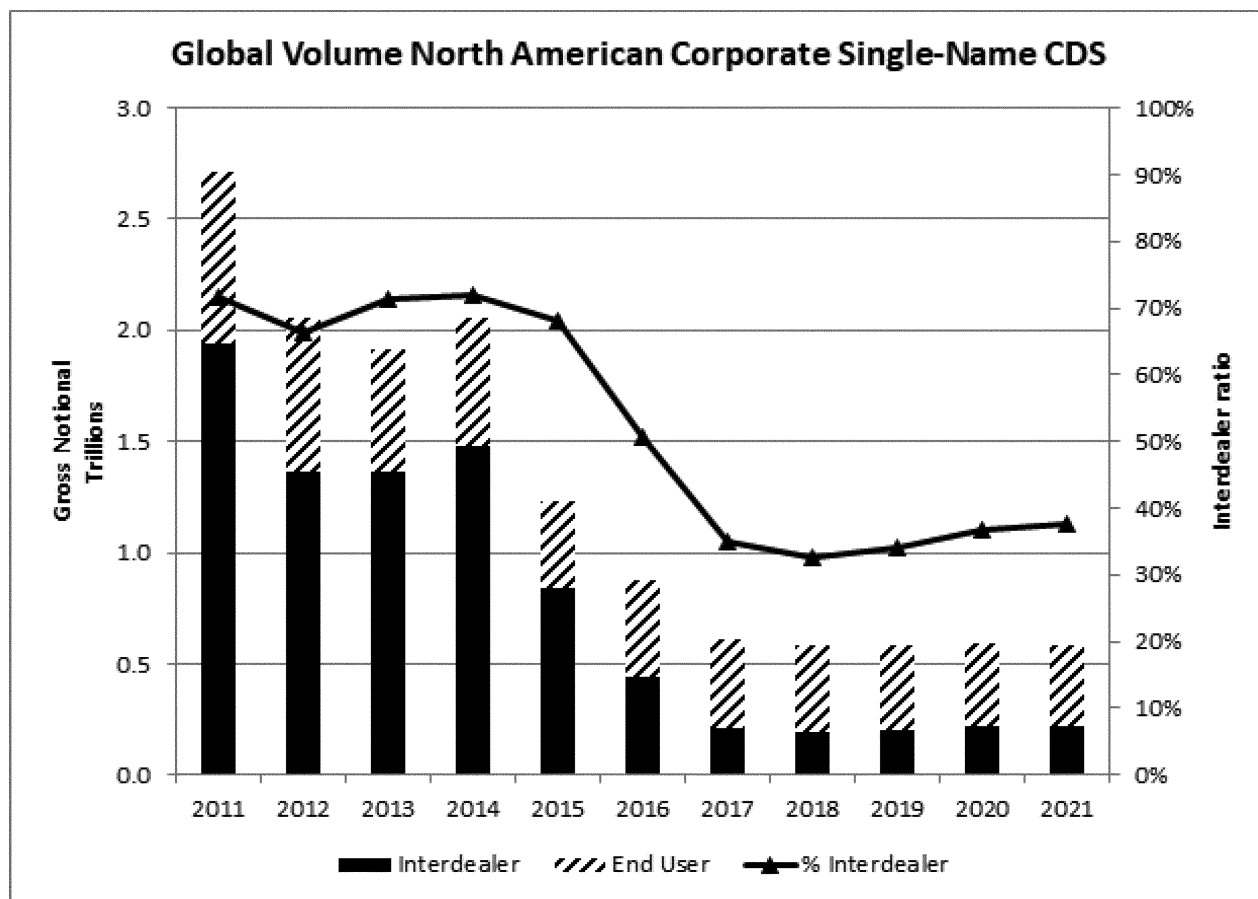
between two ISDA-recognized dealers (interdealer transactions) or whether a transaction has at least one non-dealer counterparty. Figure 1 also depicts the notional trading volume of all North American corporate single-name CDS.

As Figure 1 shows, all types of exposures have declined approximately proportionally since 2011.

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³⁰² Each transaction has two transaction sides, *i.e.*, two transaction counterparties.

Figure 1:



SOURCE: DTCC CDS – TIW. Global, notional trading volume in North American corporate single-name CDS (left axis) by calendar year and the fraction of volume that is interdealer (right axis). Same-day cleared trades are assumed to be either interdealer or between a dealer and an end-user (as security-based swap transactions between two end-users are rare in both the cleared and uncleared markets).

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D. Benefits and Costs of Rule 9j-1

1. Benefits

Rule 9j-1 would decrease fraudulent activity and litigation costs, and could decrease compliance costs. In addition, Rule 9j-1 may indirectly increase price efficiency and decrease capital costs of underlying entities. The Commission discusses each of these individual benefits in more detail below.

Rule 9j-1 would reduce the risk of fraud in the security-based swap market, including the risk of opportunistic trading strategies to the extent that such strategies occur in connection with effecting or attempting to effect any transaction in any security-based swap, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination

(prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security based-swap). The additional specificity offered by Rule 9j-1 may enhance Commission oversight of the security-based swap market, which may ultimately benefit market participants through reducing the risk of fraud. Any reduction in the risk of fraud as a result of Rule 9j-1 would be limited to the extent that the fraudulent, manipulative, and deceptive conduct by security-based swap market participants is currently subject to the general antifraud and anti-manipulation provisions of the Federal securities laws, including but not limited to sections 9(a) and 10(b) of the Exchange Act, and Rule 10b-5 thereunder, and section 17(a) of the Securities Act. To the extent that Rule 9j-1 reduces the risk of fraud, the rule could encourage

participation in the security-based market, which may result in increased competition.³⁰³ More security-based swap entities would be willing to supply (issue) and/or demand (buy) security-based swaps, with increased confidence that their counterparties would have limited abilities to impact the market through fraudulent conduct.

Rule 9j-1 may provide additional precision and specificity regarding the application of existing antifraud and anti-manipulation laws to misconduct in the security-based swap market, which could prompt some market participants to devote greater resources to ensure that they are compliant with their obligations under antifraud and anti-manipulation laws, which could also decrease the risk of fraud in the security-based swap market. Because of this decreased risk of fraud, market participants may have fewer disputes

³⁰³ See 2019 Joint Statement, *supra* note 53.

with their counterparties regarding security-based swap contracts, which in turn, could lower litigation costs for security-based swap participants and underlying entities. Lower litigation costs could contribute to reducing the cost of CDS and, to the extent that the cost of CDS is reduced, lower costs of borrowing to the underlying entity. Rule 9j–1 may also decrease compliance costs for some market participants who may, as a result of the additional specificity of the rule, need to spend fewer resources determining appropriate compliance under section 9(j).

Decreased risk of fraud in the security-based swap market may also lead to increased price efficiency, as more trading could lead to a greater exchange of market expectations from buyers and sellers transacting in the market. Further, by providing specificity, Rule 9j–1 would help prevent prohibited conduct from distorting the market and artificially increasing or decreasing security-based swap prices, which also would help to ensure more efficient pricing. Increased price efficiency would consequently lead to greater security-based swap market efficiency, as security-based swap prices would provide greater confidence that their prices more likely reflect fundamental values and risk in more liquid markets. For example, the prices of single-name CDS contracts would more likely reflect the fundamental credit risk of the underlying entity, as opposed to counterparty credit risk, or the probability that fraudulent activity prohibited by Rule 9j–1 is being perpetrated in connection with the CDS contracts.³⁰⁴

Increased participation and price efficiency in the security-based swap market as a result of Rule 9j–1 could encourage lenders to make greater use of security-based swaps for hedging their loans, which in turn could increase lending activity and capital formation.³⁰⁵

In addition, improvements in the security-based swap market as a result of Rule 9j–1 may in turn have a positive impact on capital formation and the cost of capital for the underlying entities. The market participation increases in security-based swaps may enhance liquidity in the underlying market and related swap indices, and, in general, lower the cost of capital for entities

referenced by security-based swaps.³⁰⁶ If single-name CDS prices are more reflective of the fundamental credit risk of the underlying entity, as a second order effect, participants in the market for the underlying security would be better informed about the underlying security's attributes through the CDS price signal, likely increasing their willingness to re-enter or engage in the underlying security's market. Specifically, the underlying security market uses the derivative market to assess its quality, as the derivative market in some circumstances is forward looking, liquid, and more informative than the underlying market.³⁰⁷ Greater activity in the underlying security market due to increased price efficiency and greater availability to hedge these securities in the security-based swap market could lead to lower capital costs and increase capital formation for the underlying entities. To the extent that increased capital formation for the underlying entities is associated with the issuance of a greater variety of securities, investors could benefit because they will have a larger set of investment opportunities with which to meet their investment goals.

Comments Received

In the 2021 Proposing Release, the Commission solicited feedback on, among other things, the benefits of the proposed rules, including re-proposed Rule 9j–1.³⁰⁸ One commenter strongly agreed with the Commission's discussion regarding the beneficial effects of greater participation in the security-based swap markets on liquidity in the underlying market and related swap indices, and the cost of capital for security-based swap referenced entities. The commenter also strongly agreed with the Commission's discussion regarding the value of the derivative market to the underlying security market for assessing the security market's quality.³⁰⁹

Three commenters believed that re-proposed Rule 9j–1's anticipated benefit of reduced fraudulent and manipulative

activity in the security-based swap market would not materialize.³¹⁰ Three commenters stated that the adoption of the ISDA Amendments has reduced the use of opportunistic strategies, such as manufactured credit events,³¹¹ while two of these commenters stated that the use of anti-net short provisions in the syndicated bank loan market has also had this effect.³¹² One commenter observed that opportunistic strategies have been, on the whole, extremely infrequent and doubted that re-proposed Rule 9j–1 will result in any market-wide benefit from addressing these strategies or significantly reduce manipulative activity in the security-based swap markets.³¹³ One commenter provided CDS pricing data (in the form of the difference between the CDS spread and underlying cash bond implied credit spread (“CDS-cash basis”) and interpreted those data to suggest that CDS protection buyers perceived the risk of certain opportunistic strategies to be low. The commenter then reasoned that because CDS protection buyers perceived the risk of such strategies to be low, re-proposed Rule 9j–1 would not generate the anticipated benefit of reducing fraudulent activity in the security-based swap market as well as encouraging market participation.³¹⁴

The Commission has considered feedback from the commenters who argued that the proposed rule would not have the benefit of reducing fraudulent and manipulative activity in the security-based swap market. The provisions in Rule 9j–1 are designed generally to prohibit a range of fraudulent, manipulative, and deceptive conduct in the security-based swap market. The rule is not solely intended to address opportunistic strategies in the CDS market.³¹⁵ Further, anti-net short

³¹⁰ See LSTA Letter at 4; July 2022 MFA Letter at 4–10; Milbank Letter at 8–9.

³¹¹ *Id.*

³¹² See LSTA Letter at 4; July 2022 MFA Letter at 4–10.

³¹³ Milbank Letter at 9.

³¹⁴ July 2022 MFA Letter at 2–4. The commenter referred to opportunistic strategies undertaken by CDS sellers to affect the likelihood of a credit event and the cost of CDS through actions such as changing the supply of deliverable obligations and offering financing to restructure a reference entity. See 2021 Proposing Release, 87 FR at 6655.

³¹⁵ As discussed earlier in this section, Rule 9j–1 would, among other things, reduce the risk of opportunistic trading strategies to the extent that such strategies occur in connection with effecting or attempting to effect any transaction in any security-based swap, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security based-swap).

³⁰⁴ See generally Fletcher Letter at 3 (discussing the effects of engineered CDS transactions).

³⁰⁵ See generally LSTA Letter at 2 (stating that security-based swaps “play an important in risk management and hedging in the loan markets . . . [and] facilitate lending activity by transferring some or all of the risks associated with lending . . .”).

³⁰⁶ See Martin Oehmke & Adam Zawadowski, *Synthetic or Real? The Equilibrium Effects of Credit Default Swaps on Bond Markets*, 28 Rev. of Fin. Stud. 3303–3337 (2015) and Ilhyock Shim & Haibin Zhu, *The Impact of CDS trading on the Bond Market: Evidence from Asia*, 40 J. of Banking & Finance 460–475 (2014).

³⁰⁷ See Haibin Zhu, *An Empirical Comparison of Credit Spreads Between the Bond Market and the Credit Default Swap Market*, 29 J. of Fin. Serv. Rsch. 211–235 (2006) and Jongsub Lee, et al., *When do CDS Spreads Lead? Rating Events, Private Entities, and Firm-Specific Information Flows*, 130 J. of Fin. Econ. 556–578 (2018).

³⁰⁸ 2021 Proposing Release, 87 FR at 6701–02.

³⁰⁹ Milbank Letter at 10, n.17.

provisions and ISDA Amendments are narrowly focused and have limited ability to reduce fraudulent and manipulative activity in the security-based swap market. As discussed in the 2021 Proposing Release, the ISDA Amendments would not address all of the concerns identified in the 2019 Joint Statement, including but not limited to addressing opportunistic strategies that do not involve narrowly tailored credit events.³¹⁶ Anti-net short provisions are limited to syndicated bank loans and would not apply to fraudulent activity in the security-based swap market that does not involve such loans. Thus, even if these industry efforts were successful in reducing fraudulent activity, their impact likely would be limited by their narrow scope.

In response to the comment that opportunistic strategies have been, on the whole, extremely infrequent so that re-proposed Rule 9j-1 will not result in any market-wide benefit, the Commission reiterates that the provisions in Rule 9j-1 are designed generally to prohibit a range of fraudulent, manipulative, and deceptive conduct in the security-based swap market. The rule is not solely intended to address opportunistic strategies in the CDS market.³¹⁷ Thus, even if opportunistic strategies were no longer implemented, final Rule 9j-1 would benefit the security-based swap market by prohibiting all other types of fraudulent, manipulative, and deceptive conduct in the market. That said, this benefit likely would be limited to the extent that the fraudulent, manipulative, and deceptive conduct by security-based swap market participants is currently subject to the general antifraud and anti-manipulation provisions of the Federal securities laws, including but not limited to sections 9(a) and 10(b) of the Exchange Act, and Rule 10b-5 thereunder, and section 17(a) of the Securities Act.

The Commission is not persuaded that the CDS-cash basis data provided by one of the commenters necessarily indicate that CDS protection buyers perceived the risk of certain opportunistic strategies to be low.³¹⁸ Apart from such perceived risk, the academic literature suggests a number of factors that affect the CDS-cash basis such as funding cost, counterparty risk, collateral quality, and the CDS reference entity's financial characteristics.³¹⁹

Without accounting for the influence of these other factors, it is not clear if the CDS-cash basis reflects that CDS protection buyers perceive the risk of certain opportunistic strategies to be low. Even if the CDS-cash basis data reflect CDS protection buyers' perceived risk of certain opportunistic strategies, the data's limited scope provides no information on the perceived risk of other types of fraudulent and manipulative activity in the security-based swap market. Accordingly, the commenters have not offered convincing evidence that Rule 9j-1 will be without benefits. The Commission continues to believe that Rule 9j-1, by addressing the security-based swap market more broadly, would reduce fraudulent and manipulative activity in this market.

One commenter asserted that proposed Rule 9j-1(b) (adopted as Rule 9j-1(a)(6)) would introduce substantial uncertainty in the application of the antifraud and anti-manipulation provisions of the Federal securities laws, and therefore questioned whether the benefits of "additional precision and specificity" that the Commission identified would materialize.³²⁰ Final Rule 9j-1(a)(6)'s scienter requirements, the practical utility of the rule's objective facts-and-circumstances requirement, and the applicability of familiar case law help mitigate any uncertainty that market participants may have regarding the application of the final rule.

2. Costs

Some security-based swap market participants may incur costs associated with taking actions to update existing compliance systems for compliance with Rule 9j-1. The Commission estimates that security-based swap market participants may incur one-time aggregate costs ranging between \$1,225,360 and \$2,450,720 to update their existing compliance systems.³²¹

(2019) and Amrut Nashikkar, *et al.*, *Liquidity and Arbitrage in the Market for Credit Risk*, 46 J. of Fin. Quantitative Analysis 627-656 (2011).

³²⁰ See Milbank Letter at 5, 9.

³²¹ The Commission estimates that a security-based swap market participant that updates its existing compliance system likely will do so by having a compliance attorney make a one-time update to its policies and procedures. Costs per entity = 1 hour × \$424/hour national hourly rate for a compliance attorney = \$424. The per-hour figure for a compliance attorney is from SIFMA's Management and Professional Earnings in the Securities Industry—2013, as modified by Commission staff to adjust for inflation (through Dec. 2022) and to account for an 1,800-hour work-year, and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead. Based on an analysis of information reported pursuant to Regulation SBSR to DDR and ITV, the Commission

These additional costs could be limited to the extent that many of these practices and systems are already in place to ensure compliance with section 9(j) of the Exchange Act and the other general antifraud and anti-manipulation statutory and regulatory provisions.

In addition, the rule could discourage some legitimate market activities, including some hedging activity, because of concerns that such activities might be viewed as rule violations. As a result, compliance costs related to evaluating whether or not certain activities are permissible may increase for some market participants.

Market participants might incur costs associated with the affirmative defenses in Rule 9j-1(e). However, such costs likely would be very limited. As a general matter, the affirmative defenses in Rule 9j-1(e) are voluntary and do not impose requirements on market participants. Market participants choose to incur costs related to the affirmative defenses if they anticipate the associated benefits to exceed the associated costs. Market participants for whom the anticipated benefits of the affirmative defenses do not exceed the associated costs likely would not incur those costs. However, market participants that choose not to rely on the affirmative defenses may incur other costs (e.g., additional cost of counsel or other experts to evaluate whether actions taken without relying on the affirmative defenses are compliant with the Exchange Act and Commission regulations, and a potential increase in legal liability risk).

estimates that there are 11,559 security-based swap market participants (including SBS Entities) as of Nov. 25, 2022. There is uncertainty as to how many security-based swap market participants will choose to update their existing compliance systems to comply with Rule 9j-1. A lower bound estimate is $25\% \times 11,559 = 2,889.75$, or approximately 2,890 security-based swap market participants. An upper bound estimate is $50\% \times 11,559 = 5,779.50$ or approximately 5,780 security-based swap market participants. The lower bound estimate of one-time aggregate costs = $2,890 \times \$424 = \$1,225,360$. The upper bound estimate of one-time aggregate costs = $5,780 \times \$424 = \$2,450,720$. There is also uncertainty regarding the specific changes that security-based swap market participants may make to their existing compliance systems to comply with Rule 9j-1. Two commenters believed that re-proposed Rule 9j-1 would require market participants to incur costs to design and implement extensive compliance programs and reconcile the scope of the new rule with existing practices. See LSTA Letter at 9-10; IACPM Letter at 4. However, these commenters did not provide quantified estimates of such costs. To the extent that security-based market participants choose to comply with final Rule 9j-1 in the manner described by these commenters, the costs of complying with the final rule could be higher than the Commission's estimate. To the extent that market participants incur compliance costs as a result of Rule 9j-1, these costs represent a reasonable trade-off in light of the benefits discussed in section V.D.1. See also discussion later in this section.

³¹⁶ See 2021 Proposing Release, 87 FR at 6655 n.31; *supra* note 52.

³¹⁷ See *supra* note 315.

³¹⁸ See July 2022 MFA Letter at 2-4.

³¹⁹ See, e.g., Jennie Bai & Pierre Collin-Dufresne, *The CDS-Bond Basis*, 48 Fin. Mgmt., 417-439

Market participants that seek to rely on the affirmative defense in paragraph (e)(1) of Rule 9j-1 likely would do so by creating and retaining the written security-based swap documentation governing such transaction or any amendment thereto. As discussed in the 2021 Proposing Release, such documentation is already created and retained as a result of SBS Entities' compliance with existing 17 CFR 240.15Fi-5 and the Commission's recordkeeping requirements in 17 CFR 240.17a-4 or 17 CFR 240.18a-6, as applicable.³²² Thus, the costs that may be incurred by those market participants that wish to rely on the affirmative defense likely would be very limited, if any.

Market participants that seek to rely on the affirmative defense in paragraph (e)(2) of Rule 9j-1 would be required to comply with the specific provisions of that paragraph, including implementing reasonable policies and procedures to prevent insider trading. For most market participants to whom this affirmative defense would be relevant, the costs associated with policies and procedures likely would be very limited. As discussed above, most security-based swap market participants have spent considerable resources to avail themselves of the affirmative defense of Rule 10b5-1(c)(2).³²³ Because the affirmative defense of Rule 9j-1(e)(2) is modeled on that of Rule 10b5-1(c)(2), most security-based swap market participants likely would employ their existing policies and procedures to avail themselves of the affirmative defenses of both Rules 10b5-1(c)(2) and 9j-1(e)(2).

Comments Received

One commenter believed that the proposed rules would help to reduce costs for all investors by removing fraud and manipulation from the security-based swap market and the market for underlying securities.³²⁴ However, several commenters were concerned that re-proposed Rule 9j-1 would significantly increase compliance costs for security-based swap market participants in various ways.

One commenter believed that re-proposed Rule 9j-1 would require market participants to incur costs to design and implement extensive compliance programs to adhere to the rule's broad prohibitions; and that such costs are only marginally alleviated by the narrow proposed safe harbors, since ensuring that each activity falls within

a designated safe harbor presents resource challenges of its own. The commenter stated that such compliance costs would be unreasonably burdensome to lenders and would have a significant, negative impact on the loan markets. The commenter also stated that, absent an affirmative defense similar to Rule 10b5-1(c)(2), market participants may have to incur cost and effort to identify all security-based swaps and related reference underlying entities held by the organization and to track and coordinate all activity that could affect the purchase, sale, payments, deliveries, and other ongoing obligations or rights with respect to the security-based swaps and the related reference underlying entities.³²⁵ Another commenter stated that re-proposed Rule 9j-1 would entail further significant costs and challenges because market participants would need to reconcile the scope of the new rule with existing practices.³²⁶

The Commission has considered the above comments in finalizing Rule 9j-1. As discussed above and in the 2021 Proposing Release, some security-based swap market participants may incur costs associated with taking actions to update existing compliance systems for compliance with Rule 9j-1. These additional costs could be limited to the extent that many of these practices and systems are already in place to ensure compliance with section 9(j) and the other general antifraud and anti-manipulation statutory and regulatory provisions. To the extent that market participants incur compliance costs as a result of Rule 9j-1, these costs represent a reasonable trade-off in light of the benefits discussed in section V.D.1. With respect to the identification, tracking, and coordination activities that might be necessary absent an information barrier safe harbor, final Rule 9j-1(e)(2) provides an affirmative defense modeled on the affirmative defense in Rule 10b5-1(c)(2). Final Rule 9j-1(e)(2) will help mitigate the cost and effort that market participants may incur to identify, track, and coordinate activities involving security-based swaps and related reference underlying entities held by the organization.

Several commenters were concerned that re-proposed Rule 9j-1's liability standards are vague and that such vagueness would foster significant uncertainty among security-based swap market participants, resulting in reduced market participation, liquidity, capital formation, and investor

choice.³²⁷ In response to these concerns, the Commission clarifies the liability standards of Rule 9j-1 in section II of this release. Specifically, the liability standards in the rule follow the well-settled standards in section 10(b) of the Exchange Act, and Rule 10b-5 thereunder, section 17(a) of the Securities Act, and applicable case law. The Commission also explains why a non-scienter-based standard is appropriate for paragraphs (a)(3) and (a)(4) of final Rule 9j-1 and is consistent with sections 17(a)(2) and (3) of the Securities Act, on which they are based.

Where commenters noted a discrepancy in the Commission's proposed rule and the legal standard for certain attempted offenses, the Commission revised the rule to conform to the legal standard in new Rule 9j-1(a)(5). These revisions should address any uncertainty that security-based swap market participants may have regarding the rule's liability standards. In addition, the Commission is adopting Rule 9j-1(e), which includes two affirmative defenses for violations of the provisions in paragraphs (a)(1) through (a)(5) of Rule 9j-1.³²⁸ The final rule conforms the affirmative defenses in Rule 9j-1(e) to those in existing Rule 10b5-1(c). The revisions regarding the liability standards of Rule 9j-1 coupled with the affirmative defenses of Rule 9j-1(e) should mitigate any potential adverse effects on market participation, liquidity, capital formation, and investor choice. Moreover, by reducing the risk of fraudulent and manipulative activity in the security-based swap market, Rule 9j-1 would increase market participation, liquidity, capital formation, and investor choice thereby further mitigating the potential adverse effects that commenters identified.³²⁹

One commenter was concerned that the inclusion of interim actions in the performance of contractual obligations within the scope of re-proposed Rule 9j-1 will discourage market participants from transacting in security-based swaps, reduce liquidity in the security-based swap markets, increase the cost of capital, and reduce the availability of capital.³³⁰ The Commission does not believe the final rule will adversely affect market participation, liquidity, cost of capital, and availability of capital in the manner described by the commenter. Final Rule 9j-1 applies to fraudulent, deceptive, or manipulative

³²² See 2021 Proposing Release 87 FR at 6662 n.88.

³²³ See *supra* sections II.E.2 and V.C.1.

³²⁴ Michael Comments at 1.

³²⁵ LSTA Letter at 9-10.

³²⁶ IACPM Letter at 4.

³²⁷ See IACPM Letter at 4-5; IIB-ISDA-SIFMA Letter at 1-3, 5, 13-14; LSTA Letter at 3, 5, 7; Milbank Letter at 1-5, 7, 9-10; July 2022 MFA Letter at 1, 6, 7.

³²⁸ See final Rule 9j-1(e).

³²⁹ See *supra* section V.D.1.

³³⁰ MFA Letter at 2, 8-9.

misconduct related to the exercise of any right or performance of any obligation under a security-based swap if such misconduct occurs in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, a security-based swap. Moreover, the rule addresses actions taken outside the ordinary course of a typical lender-borrower relationship (or a prospective lender-borrower relationship). Accordingly, by reducing the risk of fraudulent and manipulative activity in the security-based swap market, Rule 9j–1 will increase liquidity in the markets for security-based swaps and underlying cash instruments, and lower capital costs and increase capital formation for reference underlying entities.³³¹

Some commenters were concerned that the Commission's choice of a negligence standard for re-proposed Rules 9j–1(a)(3) and (4), coupled with the omission of Rule 10b5–1(c)(2) affirmative defenses, would discourage market participants from entering into security-based swaps and would, as a result, reduce liquidity in security-based swap markets, exacerbate risks for market participants, and increase issuers' cost of capital. These commenters were concerned that lenders may also reduce their lending activities, which would reduce financing to private companies.³³² In response to comments received on the 2021 Proposing Release, paragraphs (a)(3) and (a)(4) of new Rule 9j–1 describe conduct for which a non-scienter based standard would apply, while paragraph (a)(5) of new Rule 9j–1 describes attempts of that conduct for which scienter is the proper standard. In addition, Rule 9j–1(e)(2) provides for an affirmative defense that is modeled on the affirmative defense in Rule 10b5–1(c)(2). These changes from re-proposed Rule 9j–1 should address the commenters' concerns and mitigate any potential adverse effects on liquidity, risks, cost of capital, and financing to private companies.

Some commenters stated that proposed Rule 9j–1(b) would create uncertainty and implicate a wide range of innocuous and ordinary course activities that are essential to markets in both security-based swaps and underlying cash instruments. The commenters stated that this would materially increase compliance costs for security-based swap market participants, reduce participation in

security-based swap and securities markets, reduce lending activity and capital formation, and raise issuers' cost of capital.³³³ As discussed above, final Rule 9j–1(a)(6), as revised from proposed Rule 9j–1(b), will apply to conduct undertaken in connection with effecting or attempting to effect a transaction in any security-based swap, and to purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security based-swap). Rule 9j–1(a)(6) also prohibits the manipulation (or attempted manipulation) of the valuation of any security-based swap, or any payment or delivery related thereto, to the extent such misconduct is in connection with effecting or attempting to effect a transaction in, or purchasing or selling, or inducing or attempting to induce the purchase or sale of, any security-based swap. The final rule strikes an appropriate balance between preventing manipulation and attempted manipulation in the security-based swap market and addressing commenters' concern. A narrowing in the scope of final Rule 9j–1(a)(6) would create a gap in the prohibition against manipulation and attempted manipulation in the security-based swap market and reduce the benefits of the rule.

A determination as to whether a person has violated final Rule 9j–1(a)(6) will depend on the facts and circumstances of each particular situation. Further, a scienter standard will be used to determine whether conduct is in violation of the rule. With respect to the loan market, final Rule 9j–1(a)(6) applies to actions taken outside the ordinary course of a typical lender-borrower relationship, such as an action taken for the purposes of avoiding or causing, or increasing or decreasing, a payment under a security-based swap in a manner that would not have occurred but for such actions, or when an action appears to be designed almost exclusively to harm counterparties, and is not intended to discourage lenders from discussing or providing financing or relief to avoid default. To be clear, Rule 9j–1(a)(6) will require that security-based swap market participants take care that their legitimate market activities remain within the scope of the

typical lender-borrower relationship and do not cross the line into prohibited manipulation. The foregoing discussion should help address concerns related to uncertainty that the rule may create and the proposed rule's scope.

However, to the extent that market participants continue to have such concerns, final Rule 9j–1(a)(6) could increase compliance costs, reduce market participation, reduce lending activity and capital formation, and raise issuers' cost of capital. That said, by reducing the risk of fraudulent and manipulative activity in the security-based swap market, Rule 9j–1 would increase market participation, increase lending activity and capital formation, and lower issuers' cost of capital thereby mitigating the potential adverse effects that commenters identified. Further, to the degree that Rule 9j–1 provides additional precision and specificity regarding the application of existing antifraud and anti-manipulation laws to misconduct in the security-based swap market, some market participants may need to spend fewer resources determining appropriate compliance under section 9(j) of the Exchange Act and reduce their compliance costs.³³⁴

E. Benefits and Costs of Rule 15fh–4(c)

1. Benefits

Rule 15fh–4(c) makes it unlawful for any officer, director, supervised person, or employee of an SBS Entity, or any person acting under such person's direction, to take, directly or indirectly, any action to coerce, mislead, or otherwise interfere with the SBS Entity's CCO. This prohibition would support the ability of the CCO to meet the CCO's important obligations to foster compliance in its role of overseeing compliance within the SBS Entity. Rule 15fh–4(c) will make it more likely that a CCO is able to more efficiently and effectively execute the CCO's responsibilities to foster compliance, including for example, by ensuring that the SBS Entity maintains and reviews written policies and procedures reasonably designed to achieve compliance with the rules and regulations relating to the business of the SBS Entity. Ultimately, these effects will likely also reduce the risk of fraud, market manipulation, or other fraudulent activities in the security-based swap market, providing additional protection for both counterparties in the security-based swap transaction and the underlying entity.

³³¹ See *supra* section V.D.1.

³³² See ACLI Letter at 5–6; MFA Letter at 2, 13–16.

³³³ See MFA Letter at 16–19; Milbank Letter at 9–10.

³³⁴ See *supra* section V.D.1.

Rule 15fh–4(c) will encourage officers, directors, supervised persons, and employees of SBS Entities to exercise reasonable attention and care in their dealings with CCOs, as discussed in section III.B. To the extent that such exercise of reasonable attention and care increases the quantity and quality of information exchanged between CCOs, officers, directors, supervised persons, and employees of SBS Entities, CCOs may more efficiently and effectively foster compliance in SBS Entities. Any resulting improvement in compliance in turn could reduce the risk of fraud, market manipulation, or other fraudulent activities in the security-based swap market. More broadly, improved communication between CCOs, officers, directors, supervised persons, and employees of SBS Entities also could facilitate decision making within the SBS Entities.

Rule 15fh–4(c) would likely have minor indirect positive impacts on competition, price efficiency, and capital formation, as discussed in section V.F.

Comments Received

Two commenters believed that proposed Rule 15Fh–4(c) would deter the types of actions that prevent CCOs from performing their duties and that deterring such actions would in turn help protect the CCOs' independence and objectivity in the fulfillment of their duties.³³⁵ The Commission agrees with the commenters that Rule 15fh–4(c)'s benefit could derive in part from deterring actions that are prohibited by the rule.

2. Costs

Rule 15fh–4(c)'s prohibition on taking actions to coerce, mislead, or otherwise interfere with the SBS Entity's CCO, may create additional costs for SBS Entities. For example, to the extent that any current practices of an SBS Entity include activities that are explicitly prohibited under Rule 15fh–4(c), applicable policies and procedures will need to be updated. In addition, it is possible that the rule could cause officers, directors, supervised persons, or employees of an SBS Entity to be overly cautious when consulting with a CCO. The Commission does not, however, believe that any such effects will be significant, given the specificity of the rule's prohibition on certain interferences with the SBS Entity's CCO.

Comments Received

One commenter was concerned that the scope of the proposed rule is unclear and could lead to confusion and uncertainty as to what communications between the CCO and the officers, directors, supervised persons, and employees of the SBS Entity might violate the rule. The commenter states that such confusion and uncertainty could have a chilling effect on dialog about compliance, budget, and resource matters, which, by implication, could impede decision making within the SBS Entity.³³⁶ In response to this comment, the Commission has clarified the scope of final Rule 15fh–4(c) in section III.B. Further, the Commission clarified that the acts to “coerce, manipulate, mislead or fraudulently influence” that would be prohibited by Rule 15fh–4(c) imply compelling the CCO to act in a certain way through pressure, threats, trickery, intimidation, misrepresentation, or some other form of purposeful action not limited to untrue statements or omissions of material facts. As discussed in section V.E.1, to the extent that the rule encourages officers, directors, supervised persons, and employees of SBS Entities to exercise reasonable attention and care in their dealings with CCOs, communication and decision making could improve within the SBS Entities and mitigate any potential adverse impact on decision making suggested by the commenter.

F. Effects on Efficiency, Competition, and Capital Formation

The final rules would likely affect capital formation, competition, and efficiency in various ways, as discussed below.

1. Competition

As discussed earlier, by reducing the risk of fraud, Rule 9j–1 could encourage participation in the market, which may result in increased competition in the security-based swap market.³³⁷

Rule 15fh–4(c) would likely have a minor indirect positive impact on competition in the security-based swap market. Because Rule 15fh–4(c) would support the ability of the CCO to oversee compliance with the Federal securities laws within the SBS Entity and likely reduce the risk of fraud, security-based swaps would more likely reflect the fundamental credit risk of the underlying entity. This in turn could encourage greater participation in the security-based swap market and therefore, increase competition among the market participants.

2. Efficiency

By decreasing the risk of fraud and preventing price manipulation in the security-based swap market, Rule 9j–1 may increase price efficiency. This would consequently lead to greater security-based swap market efficiency, as security-based swap prices would provide greater confidence that their prices more likely reflect fundamental values and risk in more liquid markets.³³⁸

Rule 15fh–4(c) would likely have a minor indirect positive impact on price efficiency. To the extent that the rule increases participation in the security-based swap market as discussed in section V.F.1, price efficiency may increase because increased trading by market participants could incorporate more information into security-based swap prices.

3. Capital Formation

Final Rule 9j–1 likely would have a positive impact on capital formation. As discussed earlier, greater activity in the underlying security market due to increased price efficiency and greater availability to hedge these securities in the security-based swap market could lead to lower capital costs and increase capital formation for the underlying entities. Increased participation and price efficiency in the security-based swap market as a result of Rule 9j–1 could encourage lenders to make greater use of security-based swaps for hedging their loans, which in turn could increase lending activity and capital formation.³³⁹ To the extent that the rule lowers litigation costs and compliance costs for market participants and underlying entities, these market participants and entities could in turn use the resources that are freed up to invest in projects.

As discussed in section V.D.2, a number of commenters were concerned that re-proposed Rule 9j–1's compliance costs, scope, and liability standards would reduce capital formation (including financing to private companies) and increase the cost of capital, among other potential effects. As discussed in that section, compliance costs could be limited by existing practices and systems that are in place to comply with section 9(j) and the other antifraud and anti-manipulation provisions; that the rule's use of clear, consistent, and familiar liability standards reduces uncertainty; and that the rule's beneficial effects on capital formation and the cost of capital

³³⁵ See Better Markets Letter at 14; NYC Bar Letter at 4–5.

³³⁶ IIB–ISDA–SIFMA CCO Letter at 1–2.

³³⁷ See *supra* section V.D.1.

³³⁸ *Id.*

³³⁹ *Id.*

would mitigate any potential adverse effects that commenters identified.

Rule 15fh–4(c) would likely have a minor indirect positive impact on capital formation. To the extent that the rule increases price efficiency and competition in the security-based swap market, as discussed in sections V.F.1 and V.F.2, capital formation could, as a result, further indirectly increase, as greater price efficiency and competition among market participants could lead to a decrease in security-based swaps prices, and in turn, lower costs of borrowing (as a result of lowering the cost of CDS).

G. Reasonable Alternatives

The Commission considered a number of alternatives when finalizing Rules 9j–1 and 15fh–4(c).

1. Narrow the Scope of Rule 9j–1

Commenters recommended narrowing the scope of re-proposed Rule 9j–1 in various ways: (1) exclude valuation, payment, and delivery from the scope of proposed Rule 9j–1(b);³⁴⁰ (2) exclude certain credit market conduct from the scope of proposed Rule 9j–1(b);³⁴¹ and (3) exclude security-based swaps referencing sovereign debt from the scope of re-proposed Rule 9j–1.³⁴²

The Commission has considered these alternatives but determined that the adopted approach is preferable to them. With respect to the exclusion of valuation, payment, and delivery from the scope of proposed Rule 9j–1(b), the Commission declines to adopt this alternative. The Commission is concerned that the alternative would create a gap in the prohibition against the manipulation and attempted manipulation of prices in the security-based swap market and reduce the benefits of final Rule 9j–1(a)(6), as revised from proposed Rule 9j–1(b). The exclusion of valuation, payment, and delivery from the scope of final Rule 9j–1(a)(6) could increase the occurrence of manipulation and attempted manipulation of security-based swap prices in connection with such activities.

With respect to the exclusion of certain credit market conduct, the Commission believes it cannot specify all possible types of misconduct that may prevail in the future. Hence, provisions designed to exclude certain legitimate credit market conduct could unintentionally apply to activities that final Rule 9j–1(a)(6), as revised from

proposed Rule 9j–1(b), is designed to prohibit, reducing the benefits of the rule. Further, an exclusion of certain credit market conduct would need to be balanced against the risk that market participants undertake transactions for which their counterparties should have the protections of final Rule 9j–1(a)(6). In addition, as discussed in section II.C.2, the fact that the Commission intends to apply a scienter standard in connection with final Rule 9j–1(a)(6), and that the rule does not impose liability for actions taken in the ordinary course of a typical lender-borrower relationship (or a prospective lender-borrower relationship), should help mitigate concerns regarding any “chilling effects” of the rule.

With respect to the exclusion of sovereign debt security-based swaps, as a general matter, the Commission does not see a compelling reason to treat security-based swaps referencing sovereign underliers differently than security-based swaps referencing other underliers. As discussed in section II.E.2.d, while security-based swaps related to sovereign debt may have lesser opportunity for manufactured credit events or opportunistic strategies by regulated and non-regulated market participants alike, such instruments are not without risk of fraudulent and manipulative conduct and should remain within the scope of Rule 9j–1.³⁴³ Further, the Commission is concerned that the alternative would create a gap in the prohibition against fraudulent and manipulative activity in the security-based swap market. Even if, as the commenter asserted, manufactured credit events related to a country’s sovereign debt are unlikely, other types of fraudulent and manipulative activities could be perpetrated in connection with sovereign debt security-based swaps.³⁴⁴ The alternative would not prohibit these activities and could increase their occurrence. In light of the above, the adopted approach is preferable to this alternative.

2. Safe Harbors

Commenters suggested that the Commission add various safe harbors to Rule 9j–1. The Commission discusses these alternatives below.

a. Safe Harbor for Hedging Exposure Arising Out of Lending Activities

One commenter urged the Commission to consider creating a safe

harbor to re-proposed Rule 9j–1 for entering into security-based swap transactions for purposes of hedging some or all exposure arising out of lending activities with a reference entity or the syndication of such lending activities.³⁴⁵ Such a safe harbor could minimize the effects of the rule on risk-reducing hedging activity, which is one of the central purposes of CDS contracts and which provides important benefits to the lending market. Identifying legitimate, risk-reducing hedging activity—undertaken with the intent of covering potential losses in a position—and distinguishing such activity from other types of speculative transactions would likely be difficult. Hence, even a safe harbor designed to apply solely to legitimate hedging transactions could unintentionally apply to activities that Rule 9j–1 is designed to prohibit, reducing the benefits of the rule. Further, such a safe harbor would need to be balanced against the risk that market participants undertake transactions for which their counterparties should have the protections of Rule 9j–1, including in circumstances involving potentially opportunistic trading strategies. In light of the above, the adopted approach is preferable to this alternative.

b. Safe Harbors for Lender Disclosure, Centralized Market Activities, and Legitimate Restructurings

One commenter urged the Commission to consider allowing the lender to avoid liability under re-proposed Rule 9j–1 by disclosing to the counterparty that it is a lender to the borrower and may have material nonpublic information from the borrower.³⁴⁶ Another commenter urged the Commission to provide safe harbors for certain centralized market activities: (1) multilateral amendment exercises (including ISDA protocols) or bilateral equivalents; and (2) participation in determination committees in accordance with the determination committees’ rules and any applicable codes of conduct.³⁴⁷ A third commenter suggested that the Commission provide a safe harbor or exception for legitimate restructurings to avoid limiting the supply of funds to issuers during a restructuring.³⁴⁸ The affirmative defenses in Rule 9j–1(e) will serve the same purpose as these alternatives by permitting persons to enter into certain types of activity, pursuant to the requirements of the affirmative

³⁴⁰ Milbank Letter at 5.

³⁴¹ See IACPM Letter at 4; IIB–ISDA–SIFMA Letter at 18–19; Milbank Letter at 4–5.

³⁴² ACLI Letter at 3, 13–14.

³⁴³ See *supra* note 244 and related discussion.

³⁴⁴ See ACLI Letter at 13 (stating that it seems unlikely that any holders of security-based swaps on sovereign debt would possess the leverage necessary to manufacture credit events related to a country’s sovereign debt).

³⁴⁵ LSTA Letter at 8.

³⁴⁶ *Id.* at 9.

³⁴⁷ IIB–ISDA–SIFMA Letter at 11–12.

³⁴⁸ Fletcher Letter at 4.

defenses, while also addressing concerns about fraud and manipulation for the entire security-based swap market. With respect to the suggested safe harbor for legitimate restructurings, identifying legitimate restructurings and distinguishing such activities from other types of speculative transactions would likely be difficult. Hence, even a safe harbor designed to apply solely to legitimate restructurings could unintentionally apply to activities that Rule 9j-1 is designed to prohibit, reducing the benefits of the rule. Further, such a safe harbor would need to be balanced against the risk that market participants undertake transactions for which their counterparties should have the protections of Rule 9j-1, including in circumstances involving potentially opportunistic trading strategies. Accordingly, the adopted approach is preferable to these alternatives.

c. Safe Harbor for Publicly Executed Strategies

One commenter requested a safe harbor from liability under proposed Rule 9j-1(b) for publicly executed strategies, where multiple parties or an independent body (such as a court or regulator) are involved. The commenter distinguished publicly executed strategies from privately executed strategies, such as a single market participant entering into an agreement with a reference entity. The commenter argued that publicly executed strategies are more difficult for a single participant to manipulate than privately executed strategies because publicly executed strategies are driven by the incentives of a broader group of participants than privately executed strategies.³⁴⁹ The Commission declines to adopt this alternative. While publicly executed strategies may be difficult for a single participant to manipulate as the commenter argued, it is not clear that such strategies would remain difficult to manipulate when a group of market participants are acting in concert to manipulate such strategies. The Commission is concerned that providing a safe harbor for publicly executed strategies would encourage manipulative activity involving a coalition of market participants. That said, the Commission appreciates that there are legitimate publicly executed strategies that are not involved in manipulative activity. In section II.C.2, the Commission discusses at length the application of final Rule 9j-1(a)(6) and believes the discussion should alleviate

concerns that legitimate publicly executed strategies may violate the rule.

d. Elimination of All Safe Harbors and Affirmative Defenses

Four commenters urged for the elimination of all safe harbors and affirmative defenses from proposed Rule 9j-1(a) liability.³⁵⁰ The adopted approach, which among other things, provides two affirmative defenses in final Rule 9j-1(e), is preferable to the alternative. As discussed in section V.D.2, the two affirmative defenses will help mitigate various adverse effects (e.g., reduced market participation) that certain commenters believed may arise as a result of Rule 9j-1. Final Rule 9j-1(e)(2) will help mitigate the cost and effort that market participants may incur to identify, track, and coordinate activities involving security-based swaps and related reference underlying entities held by the organization. At the same time, the costs that market participants may incur in connection with these affirmative defenses likely would be very limited.³⁵¹

3. Implementing a More Prescriptive Approach in Rule 9j-1

One commenter urged the Commission to consider the alternative approach of identifying and prohibiting within Rule 9j-1 specific types of events (for example, market behavior around certain events and fact patterns) and opportunistic trading behavior that have been observed. According to the commenter, this alternative approach could provide even more certainty and precision with respect to the particular types of activities that are prohibited in the security-based swap market. The commenter believed that the greater certainty of outcome with respect to Rule 9j-1 would benefit lenders when they need to exercise rights or remedies under a loan or credit agreement.³⁵² However, this approach could lead to greater uncertainty with respect to circumstances not explicitly contemplated in the rule, which could increase litigation costs for market participants involved in such transactions. This approach may also decrease the integrity of the market for security-based swaps, and in addition, could cause market participants to bear greater compliance costs in connection with the evaluation of circumstances not explicitly contemplated in the rule. As a result, the more prescriptive alternative approach would have

limited benefits and greater costs as compared to the adopted approach in the market for security-based swaps, as well as the market for the reference underlying of such security-based swaps.

The Commission acknowledges the commenter's concern that not adopting the more prescriptive alternative approach could prevent lenders or security-based swap participants from exercising legitimate rights and remedies and impose costs that would be greater than those discussed in the 2021 Proposing Release in connection with re-proposed Rule 9j-1.³⁵³ Final Rule 9j-1 would enable lenders or security-based swap participants to exercise legitimate rights and remedies, thereby addressing the commenter's concern. In particular, paragraphs (a)(3) and (a)(4) of final Rule 9j-1 describe conduct for which a non-scienter based standard would apply, while paragraph (a)(5) of final Rule 9j-1 describes attempted aspects of that conduct for which scienter is the proper standard. In addition, final Rule 9j-1(e) provides for affirmative defenses similar to the affirmative defenses in Rule 10b5-1(c). The clarification regarding the liability standards of Rule 9j-1 coupled with the affirmative defenses of Rule 9j-1(e) should mitigate any potential adverse effects on market participation, liquidity, capital formation, and investor choice. Moreover, by reducing the risk of fraudulent and manipulative activity in the security-based swap market, Rule 9j-1 would increase market participation, liquidity, capital formation, and investor choice thereby further mitigating the potential adverse effects that commenters identified.

4. Separate Rules for CDS and Equity Security-Based Swaps

One commenter asserted that opportunistic strategies work best with CDS and that equity SBS are less susceptible to such strategies. The commenter suggested that the Commission propose separate rules for each type of instrument.³⁵⁴ The Commission has considered the commenter's suggested alternative, but believes that the adopted approach is preferable to the alternative. The aim of Rule 9j-1 is to address fraud and manipulation in the security-based swap market and is not limited to addressing fraud and manipulation in connection with certain opportunistic strategies that historically have been implemented with CDS. As discussed in section II, fraudulent and manipulative

³⁵⁰ Better Markets Letter at 2, 9–12; Anonymous Penguin Comments at 1; J.T. Comments at 1; Michael Comments at 1.

³⁵¹ See *supra* section V.D.2.

³⁵² LSTA Letter at 7.

³⁵³ *Id.*

³⁵⁴ Fletcher Letter at 4.

³⁴⁹ IIB-ISDA-SIFMA Letter at 17.

conduct has the potential to harm counterparties to all forms of security-based swaps, including CDS, equity security-based swaps, and non-CDS debt security-based swaps. Rule 9j–1 is appropriately tailored to address fraud and manipulation for the entire security-based swap market. As such the Commission does not see the need to adopt separate rules for CDS and equity security-based swaps.

5. Exclude Underlying Securities

One commenter urged the Commission to modify re-proposed Rule 9j–1 by providing that its prohibitions do not extend to the purchase or sale of underlying securities.³⁵⁵ The Commission declines to adopt this alternative. Because security-based swaps by their nature are tied intrinsically to activity in other securities markets, persons that intend to perpetrate fraudulent or manipulative activity with respect to a security-based swap may choose to do so by purchasing or selling the underlying security. The alternative would create a gap in the prohibition against fraudulent and manipulative activity in connection with security-based swaps and increase the risk of such activity to the detriment of investors. In contrast, final Rule 9j–1(c) is designed so that a person cannot escape liability under section 9(j) of the Exchange Act or Rule 9j–1(a) with respect to a security-based swap by limiting all of its actions to purchases or sales of the security or narrow-based security index underlying that security-based swap.

6. Limit Activities Prohibited Under Rule 15fh–4(c)

One commenter suggested that final Rule 15fh–4(c) should limit the prohibited interference to knowingly making untrue statements or omitting material facts.³⁵⁶ As discussed in section III.B, Rule 15fh–4(c) protects the independence and objectivity of an SBS Entity's CCO by prohibiting undue influence by other personnel. Such influence could take many forms and is not limited to material misstatements or omissions. The Commission is concerned that limiting prohibited activities to material misstatements and omissions, as suggested by the commenter, would fail to adequately protect the CCO from undue influence and consequently reduce the rule's benefit. As discussed in section V.E.1, by encouraging officers, directors, supervised persons, and employees of SBS Entities to exercise reasonable

attention and care in their dealings with CCOs, final Rule 15fh–4(c) would foster compliance in SBS Entities, reduce the risk of fraudulent and manipulative conduct, and facilitate decision making in SBS Entities. The suggested alternative, by its limited nature, may be less likely to encourage such exercise of reasonable attention and care in dealings with CCOs. Accordingly, the adopted approach is preferable to the alternative.

VI. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act ("RFA")³⁵⁷ requires Federal agencies, in promulgating rules, to consider the impact of those rules on small entities. Section 603(a) of the Administrative Procedure Act,³⁵⁸ as amended by the RFA, generally requires the Commission to undertake a regulatory flexibility analysis of all proposed rules, or proposed rule amendments, to determine the impact of such rulemaking on "small entities."³⁵⁹ Section 605(b) of the RFA states that this requirement shall not apply to any proposed rule or proposed rule amendment which, if adopted, would not have a significant economic impact on a substantial number of small entities.³⁶⁰ The Commission certified in the 2021 Proposing Release that new Rules 9j–1 and 15fh–4(c) would not have a significant economic impact on any "small entity" for purposes of the RFA.³⁶¹ The Commission received no comments on its certification.

For purposes of Commission rulemaking in connection with the RFA, a small entity includes: (1) when used with reference to an "issuer" or a "person," other than an investment company, an "issuer" or "person" that, on the last day of its most recent fiscal year, had total assets of \$5 million or less;³⁶² or (2) a broker-dealer with total capital (net worth plus subordinated liabilities) of less than \$500,000 on the date in the prior fiscal year as of which

its audited financial statements were prepared pursuant to 17 CFR 240.17a–5(d) under the Exchange Act,³⁶³ or, if not required to file such statements, a broker-dealer with total capital (net worth plus subordinated liabilities) of less than \$500,000 on the last business day of the preceding fiscal year (or in the time that it has been in business, if shorter); and is not affiliated with any person (other than a natural person) that is not a small business or small organization.³⁶⁴

Based on available information about the security-based swap market, the market, while broad in scope, is largely dominated by entities such as those that will be covered by the SBS and MSBSP definitions. Based on feedback from industry participants about the security-based swap market, the Commission continues to believe that: (1) the types of entities that are and will continue to register with the Commission as SBSs (*i.e.*, because they engage in more than a de minimis amount of dealing activity involving security-based swaps)—which generally would be large financial institutions—would not be "small entities" for purposes of the RFA; and (2) the types of entities that may have security-based swap positions above the level required to register as MSBSPs would not be "small entities" for purposes of the RFA.

Although Rule 15fh–4(c) applies only to SBS Entities, Rule 9j–1 is not on its face limited to SBS Entities. However, while it is possible that other parties may engage in security-based swap transactions, the Commission does not believe that any such entities would be "small entities" as defined in Exchange Act Rule 0–10.³⁶⁵ Feedback from industry participants about the security-based swap market indicates that only persons or entities with assets significantly in excess of \$5 million (or with annual receipts significantly in excess of \$7 million) participate in the security-based swap market. With respect to Rule 9j–1, even to the extent that a small number of transactions did have a counterparty that was defined as a "small entity" under Rule 0–10, the Commission believes it unlikely that the rule would have a significant economic impact on such entities, as the rule prohibits fraudulent and manipulative acts, activities which are in most cases already prohibited.

For the foregoing reasons, the Commission certifies that Rules 9j–1 and 15fh–4(c) will not have a significant

³⁵⁵ MFA Letter at 2, 8–9.

³⁵⁶ ISDA–IIB–SIFMA CCO Letter at 2.

³⁵⁷ 5 U.S.C. 601 *et seq.*

³⁵⁸ 5 U.S.C. 603(a).

³⁵⁹ Although section 601(b) of the RFA defines the term "small entity," the statute permits agencies to formulate their own definitions. The Commission has adopted definitions for the term "small entity" for the purposes of Commission rulemaking in accordance with the RFA. Those definitions, as relevant to this rulemaking, are set forth in 17 CFR 240.0–10 ("Rule 0–10") under the Exchange Act. See Final Definitions of "Small Business" and "Small Organization" for Purposes of the Regulatory Flexibility Act, Exchange Act Release No. 18452 (Jan. 28, 1982), 47 FR 5215 (Feb. 4, 1982) (File No. S7–879).

³⁶⁰ See 5 U.S.C. 605(b).

³⁶¹ See 2021 Proposing Release, 87 FR at 6702–03.

³⁶² See 17 CFR 240.0–10(a).

³⁶³ 17 CFR 240.17a–5(d).

³⁶⁴ See 17 CFR 240.0–10(c).

³⁶⁵ See 17 CFR 240.0–10(a).

economic impact on a substantial number of small entities for purposes of the RFA.

VII. Other Matters

Pursuant to the Congressional Review Act,³⁶⁶ the Office of Information and Regulatory Affairs has designated these rules as not a “major rule,” as defined by 5 U.S.C. 804(2).

If any of the provisions of these final rules, or the application thereof to any person or circumstance, is held to be invalid, such invalidity shall not affect other provisions or application of such provisions to other persons or circumstances that can be given effect without the invalid provision or application.

Statutory Authority

The Commission is adopting the new rules and rule amendment contained in this release under the authority set forth in the Exchange Act, 15 U.S.C. 78a *et seq.*, as amended, and, particularly sections 2, 3(b), 9(i), 9(j), 10, 15, 15F, and 23(a) thereof (15 U.S.C. 78b, 78c(b), 78i(j), 78j(j), 78j, 78o, 78o–10, and 78w(a)).

List of Subjects in 17 CFR Part 240

Administrative practice and procedure, Brokers, Confidential business information, Fraud, Reporting and recordkeeping requirements, Securities, Swaps.

Text of the Final Rule

For the reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The general authority citation for part 240 continues to read, and the sectional authority for § 240.15fh–1 is revised to read, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78j–4, 78k, 78k–1, 78l, 78m, 78n, 78n–1, 78o, 78o–4, 78o–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78dd, 78ll, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.*, and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

Sections 240.15fh–1 through 240.15Fh–6 and 240.15Fk–1 are also issued under sec. 943, Pub. L. 111–203, 124 Stat. 1376.

* * * * *

§§ 240.10a–1 and 240.10a–2 [Amended]

■ 2. Move reserved §§ 240.10a–1 and 240.10a–2 from undesignated center heading “Hypothecation of Customers’ Securities” to undesignated center heading “Manipulative and Deceptive Devices and Contrivances” in numerical order.

■ 3. Add § 240.9j–1 under the undesignated center heading “Manipulative and Deceptive Devices and Contrivances” to read as follows:

§ 240.9j–1 Prohibition against fraud, manipulation, or deception in connection with security-based swaps.

(a) It shall be unlawful for any person, directly or indirectly, to effect any transaction in, or attempt to effect any transaction in, any security-based swap, or to purchase or sell, or induce or attempt to induce the purchase or sale of, any security-based swap (including but not limited to, in whole or in part, the execution, termination (prior to its scheduled maturity date), assignment, exchange, or similar transfer or conveyance of, or extinguishing of any rights or obligations under, a security based-swap, as the context may require), in connection with which such person:

(1) Employs or attempts to employ any device, scheme, or artifice to defraud or manipulate;

(2) Makes or attempts to make any untrue statement of a material fact, or omits to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading;

(3) Obtains money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(4) Engages in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person;

(5) Attempts to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or attempts to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person; or

(6) Manipulates or attempts to manipulate the price or valuation of any security-based swap, or any payment or delivery related thereto.

(b) Wherever communicating, or purchasing or selling a security (other

than a security-based swap) while in possession of material nonpublic information would violate, or result in liability to any purchaser or seller of the security under, either the Act or the Securities Act of 1933, or any rule or regulation thereunder, such conduct in connection with a purchase or sale of a security-based swap with respect to such security or with respect to a group or index of securities including such security shall also violate, and result in comparable liability to any purchaser or seller of that security under, such provision, rule, or regulation.

(c) Wherever taking any of the actions set forth in paragraph (a) of this section involving a security-based swap would violate, or result in liability under, Section 9(j) of the Act or this section, such conduct, when taken by a counterparty to such security-based swap (or any affiliate of, or a person acting in concert with, such security-based swap counterparty in furtherance of such prohibited activity), in connection with a purchase or sale of a security, loan, or group or index of securities on which such security-based swap is based, shall also violate, and shall be deemed a violation of, section 9(j) of the Act or paragraph (a) of this section.

(d) For purposes of this section, the terms “purchase” and “sale” shall have the same meanings as set forth in Sections 3(a)(13) (15 U.S.C. 78c(a)(13)) and 3(a)(14) (15 U.S.C. 78c(a)(14)) of the Act.

(e) A person shall not be liable under paragraphs (a)(1) through (a)(5) of this section solely for being aware of material nonpublic information while taking the following actions:

(1) Actions taken by a person in accordance with binding contractual rights and obligations under a security-based swap (as reflected in the written documentation governing such security-based swap or any amendment thereto) so long as the person demonstrates that:

(i) The security-based swap was entered into, or the amendment was made, before the person became aware of such material nonpublic information, and

(ii) The security-based swap was entered into in good faith and not as part of a plan or scheme to evade the prohibitions of this section.

(2) Actions taken by a person other than a natural person if the person demonstrates that:

(i) The individual making the investment decision on behalf of the person taking the action was not aware of the material nonpublic information, and

³⁶⁶ 5 U.S.C. 801 *et seq.*

(ii) The person had implemented reasonable policies and procedures, taking into consideration the nature of the person's business, to ensure that individuals making investment decisions would not be in violation of paragraphs (a)(1) through (a)(5) of this section. These policies and procedures may include those that restrict effecting a transaction in, or purchasing or selling, any security, including any security-based swap, as to which the person has material nonpublic information, or those that prevent such individuals from becoming aware of such information.

- 4. Redesignate § 240.15Fh-4 as § 240.15fh-4 and amend newly redesignated § 240.15fh-4 by:
- a. Revising the section heading; and
- b. Adding paragraph (c).

The revisions read as follows:

§ 240.15fh-4 (Rule 15fh-4) Antifraud provisions for security-based swap dealers and major security-based swap participants; special requirements for security-based swap dealers acting as advisors to special entities.

* * * * *

(c) *No undue influence over chief compliance officer.* It shall be unlawful for any officer, director, supervised person, or employee of a security-based swap dealer or major security-based

swap participant, or any person acting under such person's direction, to directly or indirectly take any action to coerce, manipulate, mislead, or fraudulently influence the security-based swap dealer's or major security-based swap participant's chief compliance officer in the performance of their duties under the Federal securities laws or the rules and regulations thereunder.

By the Commission.

Dated: June 7, 2023.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2023-12592 Filed 6-29-23; 8:45 am]

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Vol. 88, No. 125

Friday, June 30, 2023

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FEDERAL REGISTER PAGES AND DATE, JUNE

35729-36210	1
36211-36436	2
36437-36918	5
36919-37142	6
37143-37466	7
37467-37752	8
37753-37974	9
37975-38376	12
38377-38736	13
38737-39110	14
39111-39334	15
39335-39762	16
39763-39994	20
39995-40676	21
40677-41014	22
41015-41288	23
41289-41470	26
41471-41814	27
41815-42014	28
42015-42226	29
42227-42586	30

CFR PARTS AFFECTED DURING JUNE

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	203.....41015
Proclamations:	10 CFR
9980 (amended by 10588).....36437	50.....39995
10587.....35729	52.....39995
10588.....36437	72.....39119
10589.....36445	170.....39120
10590.....36447	171.....39120
10591.....36451	429.....38600, 40406
10592.....36453	430.....38600, 39912, 40406
10593.....36455	431.....36066, 36217, 36368, 36392, 40406
10594.....36459	602.....41289
10595.....38737	710.....41289
10596.....39765	712.....41289
10597.....40677	725.....41289
10598.....40679	835.....41289
Executive Orders:	850.....41289
14100.....39111	851.....41289
14101.....41815	1016.....41289
Administrative Orders:	1017.....41289
Memorandums:	1045.....41289
Memorandum of May 20, 2023.....36211	1046.....41289
Memorandum of May 25, 2023.....36213	Proposed Rules:
Memorandum of May 26, 2023.....36215	35.....38407
Memorandum of May 31, 2023.....37751	50.....41862
Memorandum of June 13, 2023.....39763	51.....38408
Notices:	52.....38408, 41862
Notice of June 12, 2023.....39109	72.....36514
Notice of June 20, 2023.....40681, 40683	100.....38408
5 CFR	430.....40932
2634.....37753	431.....35765
2635.....37753	12 CFR
Proposed Rules:	Proposed Rules:
531.....41855	34.....40638
10501.....37800	225.....40638
6 CFR	323.....40638
Ch. I.....36919, 36921	722.....40638
7 CFR	741.....40638
400.....42015	1026.....40638
407.....42015	1222.....40638
457.....42015	1236.....35780
701.....39767	1310.....41510
760.....39767	13 CFR
922.....41471	123.....39335
930.....39117	14 CFR
1735.....36217	25.....37467, 38377, 39152, 41295
Proposed Rules:	39.....35731, 36236, 36461, 36463, 36465, 36924, 36926, 36928, 36930, 36933, 37755, 37760, 37975, 38382, 38384, 38387, 39341, 39344, 39996, 40003, 40011, 40023, 40058, 40065, 40071, 40685, 41308, 41312, 41473
932.....39374	43.....38391
956.....39377	65.....38391
9 CFR	71.....35734, 36468, 36935, 36936, 37143, 37469, 38395,
201.....41015	

38396, 39161, 39162, 39164, 39165, 39166, 39167, 39168, 39346, 39347, 39349, 39350, 40695, 41313, 41314, 41315, 41819, 42227	141.....41477	100.....36237, 36238, 36949, 37145, 38398, 39770, 41820	110.....38279, 41834
91.....41023	19 CFR	117.....36241, 37470	122.....37994
97.....35735, 35737, 40081, 40083, 42228, 42230	111.....41124	147.....42237	123.....37994
121.....41295	20 CFR	165.....35741, 36243, 36245, 36476, 36477, 36950, 36951, 36952, 36954, 36955, 36956, 37147, 37149, 37471, 37472, 37762, 37764, 37992, 38398, 38406, 38748, 38749, 38751, 38753, 39170, 39172, 39358, 39360, 40713, 41027, 41029, 41320, 41500, 41502, 41504, 41506, 41507, 41508, 41820, 41822, 41824, 42027, 42028, 42030, 42243, 42245	180.....37769, 39185, 39189, 39770, 39776, 39780
147.....38391	Proposed Rules:	Proposed Rules:	300.....38279, 41834
399.....39352	402.....36980	100.....35802, 36999, 37194, 39206, 39385	372.....41035
Proposed Rules:	21 CFR	140.....38765	423.....41326
1.....38946	1301.....40707	146.....38765	702.....37155
3.....38001	Proposed Rules:	165.....35805, 38413, 39799, 40134	703.....37155
21.....37805	73.....41870	34 CFR	704.....37155
25.....35781	173.....40122	600.....39360	707.....37155
39.....35783, 35785, 35788, 36258, 37481, 37807, 37810, 37812, 38409, 38758, 38759, 38762, 39379, 39794, 39796, 41510, 41513, 41516, 41518, 41863	573.....41541	674.....39360	716.....37155
43.....38946	22 CFR	682.....39360	717.....37155
60.....38946	22.....35738	685.....39360	720.....37155
61.....38946, 41194	42.....35738	36 CFR	723.....37155
71.....36976, 36979, 37177, 37179, 37182, 37184, 37484, 38412, 39204, 39382, 39384, 41337, 42276	51.....41024	Proposed Rules:	725.....37155
91.....38946	242.....41316	200.....37485	790.....37155
91.....41045, 41194	23 CFR	228.....38416	Proposed Rules:
97.....38946	490.....36472	37 CFR	52.....35807, 36249, 36251, 36253, 37841, 38430, 38433, 38436, 38441, 38448, 39210, 39801, 40136, 40726, 41056, 41341, 41344
111.....38946	1300.....36472	1.....36247, 36956, 39172	60.....36524, 39390, 41361, 41369
135.....38946	25 CFR	41.....36247	63.....35808, 38009, 41361, 41369, 41872
136.....38946	15.....39768	202.....35741	78.....35807
141.....38946	575.....41025	381.....41827	97.....35807
142.....38946	26 CFR	Proposed Rules:	302.....37841
194.....38946	1.....37424, 40086, 41499, 42231	201.....37486	721.....39804, 40728
15 CFR	20.....37424	38 CFR	751.....39652
4.....36469	25.....37424	38.....42245	1600.....36255
7.....39353	Proposed Rules:	Proposed Rules:	41 CFR
744.....38739, 40084	Ch. I.....35791	1.....36261, 37839	Proposed Rules:
Proposed Rules:	1.....37186, 40123, 40496, 40528, 40725, 41047, 41340	3.....36261	51–59.....40741
400.....37815	301.....40528	13.....36261	42 CFR
16 CFR	27 CFR	19.....36261	412.....37772
1272.....40086	Proposed Rules:	20.....36261	416.....36485
Proposed Rules:	6.....36515	39 CFR	417.....37174
Ch. II.....41046	8.....36515	20.....38753	418.....36485
1.....38765	10.....36515	111.....36958, 42247	422.....37174
318.....37819	11.....36515	241.....36960	423.....37174
801.....42178	28 CFR	3006.....37152	441.....36485
803.....42178	Proposed Rules:	3011.....37152, 37474	455.....37174
1281.....37185	81.....36516	Proposed Rules:	460.....36485, 37174
17 CFR	29 CFR	111.....41871	482.....36485
200.....37986	4044.....39169	3030.....39388	483.....36485
229.....36002, 37986	30 CFR	3050.....37003, 39388	484.....36485
232.....36002	Proposed Rules:	40 CFR	485.....36485
240.....36002, 39962, 42546	550.....42136	2.....37155	486.....36485
242.....39962	556.....42136	9.....37994	491.....36485
249.....36002, 37986	590.....42136	52.....36479, 36481, 36654, 36962, 37766, 38754, 39177, 39179, 39182, 39366, 40715, 41031, 41320, 42030, 42248, 42252, 42258	494.....36485
270.....37986	31 CFR	60.....41833	Proposed Rules:
274.....36002, 37986	548.....36942, 36946, 36947	75.....36654	413.....42430
275.....37986, 38145	587.....36475, 40095	78.....36654	512.....42430
279.....38145	591.....40713	97.....36654	43 CFR
Proposed Rules:	32 CFR	45 CFR	30.....39768
Ch. I.....41774	310.....42234	1302.....41326	3170.....39513
17.....41522	Proposed Rules:	Proposed Rules:	Proposed Rules:
39.....39205	1660.....41051	1321.....39568	1600.....39818
240.....41338	33 CFR	1322.....39568	2800.....39726
18 CFR	83.....37988	1323.....39568	6100.....39818
35.....37144, 40696		1324.....39568	
40.....41262			

46 CFR

502.....	41039
503.....	41039
520.....	41039
530.....	41039
535.....	41039
540.....	41039
550.....	41039
555.....	41039
560.....	41039

Proposed Rules:

4.....	38765
109.....	38765
542.....	38780

47 CFR

0.....	40096
1.....	40096
2.....	37318, 41040
25.....	39783
51.....	35743
54.....	36510
61.....	35743
64.....	40096
69.....	35743
73.....	37474

Proposed Rules:

1.....	36154
4.....	37842
9.....	37842
10.....	40606
25.....	40142
54.....	42276
64.....	37843, 42034
76.....	42277

48 CFR

Ch. I.....	36430, 36435
4.....	36430
13.....	36430
39.....	36430
52.....	36430
209.....	37793
212.....	37794
217.....	37793
224.....	37793
225.....	37794
252.....	37794, 37798
726.....	39189
729.....	39189
731.....	39189
752.....	39189
3001.....	40560

3002.....	40560
3004.....	40560
3052.....	40560

Proposed Rules:

213.....	37942
225.....	37942
252.....	37942

49 CFR

367.....	40719
371.....	39368
801.....	36964
Ch. XII.....	36919, 36921

Proposed Rules:

171.....	41541
174.....	41541
180.....	41541
191.....	42284
192.....	42284
193.....	42284
372.....	40146
571.....	37843, 38632
596.....	38632

50 CFR

14.....	38358

17.....	41724, 41835
229.....	36965
300.....	36973, 41334
622.....	37475, 39193, 40121, 42271
635.....	37175, 42272
648.....	39793
655.....	39201
660.....	37479, 41040
679.....	39203, 41043, 42032

Proposed Rules:

17.....	37490, 38455, 40160, 40742, 41560
19.....	35809
21.....	35809, 35821
22.....	35809, 35821
32.....	41058
216.....	38010
217.....	37606
300.....	39216
402.....	40753
424.....	40764
622.....	38011, 40190
648.....	35823
679.....	39216

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 June 16, 2023	Public Laws Electronic Notification Service (PENS) PENS is a free email notification service of newly	enacted public laws. To subscribe, go to <i>https://portalguard.gsa.gov/—layouts/PG/register.aspx.</i> 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.